Internship Training

At

PharmaACE, Pune

COMPETITIVE INTELLIGENCE TOOLS FOR STRATEGIC DECISION MAKING (SDM) PROCESS

By

Dr. Aishwarya Nagarajan

PG/19/007

Under the guidance of
Dr. Sumant Swain

Post Graduate Diploma in Hospital and Health Management
2019-2021

International Institute of Health Management Research
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The certificate is awarded to

Dr. Aishwarya Nagarajan

In recognition of having successfully completed her internship in the department of **Competitive Intelligence** And has successfully completed her project on

Competitive Intelligence Tools for Strategic Decision Making (SDM) Process

10.06.2021

At

PharmaACE, Pune

She comes across as a committed, sincere & diligent person who has a strong drive & zeal for learning.

We wish her all the best for future endeavors.

Aahana Aiyer

Training & Development

Pooja Cornelius

Zonal Head-Human Resources

TO WHOMSOEVER IT MAY CONCERN

This is to certify that ***Dr. Aishwarya Nagarajan*** student of PGDM (Hospital & Health Management) from International Institute of Health Management Research; New Delhi has undergone internship training at PharmaACE, Pune from 1st March to 31st May, 2021.

The Candidate has successfully carried out the study designated to him during internship training and his/her approach to the study has been sincere, scientific, and analytical.

The Internship is in fulfillment of the course requirements.

I wish him all success in all his/her future endeavors.

Ms. Divya Aggarwal
Associate Dean, Academic and Student Affairs
IIHMR, New Delhi

Dr. Sumant Swain
Assistant Professor
IIHMR, New Delhi

Certificate of Approval

The following dissertation titled "**Competitive intelligence tools for strategic decision making (SDM) process**" at **"PharmaACE, Pune"** is hereby approved as a certified study in management carried out and presented in a manner satisfactorily to warrant its acceptance as a prerequisite for the award of **Post Graduate Diploma in Health and Hospital Management** (Hospital & Health Management) for which it has been submitted. It is understood that by this approval the undersigned do not necessarily endorse or approve any statement made, opinion expressed or conclusion drawn therein but approve the dissertation only for the purpose it is submitted.

Dissertation Examination Committee for evaluation of dissertation.

Name Signature

Dr. Preetha G.S

Dr. Sumesh Kumar

Dr. Rajeev Patni

Certificate from Dissertation Advisory Committee

This is to certify that **Dr. Aishwarya Nagarajan,** a graduate student of the **PGDM (Hospital & Health Management)** has worked under our guidance and supervision. She is submitting this dissertation titled "**Competitive intelligence tools for strategic decision making (SDM) process**" at **"PharmaACE, Pune"** in partial fulfillment of the requirements for the award of the **PGDM (Hospital & Health Management).**

This dissertation has the requisite standard and to the best of our knowledge no part of it has been reproduced from any other dissertation, monograph, report or book.

Amit Pharande

Amit Pharande

Team lead
PharmaACE Analytics,
Pune

Dr. Sumant Swain
Assistant Professor
IIHMR-Delhi

INTERNATIONAL INSTITUTE OF HEALTH MANAGEMENT RESEARCH, NEW DELHI

CERTIFICATE BY SCHOLAR

This is to certify that the dissertation titled **Competitive intelligence tools for strategic decision making (SDM) process** and submitted by Dr. Aishwarya Nagarajan Enrollment No.PG/19/007 under the supervision of Mr. Amit Pharande (Industry mentor, PharmaACE) and Dr. Sumant Swain (Internal mentor, IIHMR, Delhi) for award of PGDM (Hospital & Health Management) of the Institute carried out during the period from 1st March to 31st May, 2021 embodies my original work and has not formed the basis for the award of any degree, diploma associate ship, fellowship, titles in this or any other Institute or other similar institution of higher learning.

Dr. Aishwarya Nagarajan

FEEDBACK FORM

Name of the Student: Dr. Aishwarya Nagarajan

Dissertation Organization: PharmaACE

Area of Dissertation: Competitive Intelligence

Attendance: 100%

Objectives achieved: Aishwarya has attended all the internal training sessions and has grasped all the fundamental key skills required to for a fresher to start in Pharma Consulting Industry.

Deliverables: Pipeline cleaning, building CI landscape, launch time estimation, hiring tracker, secondary searches, clinical trial design and data analysis.

Strengths: Hardworking, smart, team player and quick learner

Suggestions for Improvement: Be proactive with communication and plan project to meet timelines.

Suggestions for Institute (course curriculum, industry interaction, placement, alumni): Nothing

Amit Pharande

Amit Pharande, Team lead in PharmaACE Analytics

Signature of the Officer-in-Charge/ Organization Mentor (Dissertation)

Date: 17.06.2021

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The completion of my summer training would not have been possible without tireless contribution and consistence of my friends and family.

Dr. Aishwarya Nagarajan

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PharmaACE Analytics LLP
Pune

About

PharmaACE operates at the intersection of science, data, technology, and business strategy. Our consultants provide clients with innovative solutions based on deep industry insights, analytical expertise, and an unbiased perspective.

With our focus on data analytics and modelling, we knew we had to deal with the unmet need around tools and technologies.

Our IT journey, therefore, started hand in hand with our consulting practice. Today, our technology experts not only create customized platforms and tools, but also work on data analytics, using Big Data and Machine Learning.

ABSTRACT

This project put lights on the concept of Competitive Intelligence (CI) and its use within the Pharmaceutical Industry. The complex nature of the pharmaceutical market in USA market, combined with intensified rivalry that happens among pharmaceutical firms, create an unstable environment forcing pharmaceutical companies to become more aware of the market's behaviours. a method to raised understand the market, so as to efficiently support business decisions, is Competitive Intelligence (CI). It also elaborates the utilization of such information gathered through CI for SDM (strategic decision making) process. For better understanding, a client Company Z having a business question about their Product A has been explained. Secondary data collected from various sources has been compiled using various CI tools to give meaningful information and analysis which in turn will help us to advice the client on the strategic way forward.

KEY WORDS

Acute and chronic Graft vs Host disease, ECP devices, treatment and prophylaxis

List of abbreviations

CI	Competitive Intelligence
SDM	Strategic Decision Making
GVHD	Graft versus Host Disease
ECP	Extra Corporeal Photopheresis

INTRODUCTION

Competitive Intelligence is the get-together and investigation of information to envision serious movement, see past market interruptions and impartially decipher occasions. It is fundamental segment to building up a business procedure. CI gives knowledge into the commercial center elements and difficulties during an organized, taught, and moral way utilizing distributed and non-distributed sources.

This study provides the key link between Competitive Intelligence, its tools and the strategic actions taken by a company to solve their business questions. The study is presented with an example of Company Z facing a business problem with their Product A.

About Company Z and its Product A:

Company Z is a key market player in the field of immunotherapy, providing an effective treatment options for prevention of immunological disorders, like cutaneous T-cell lymphoma (CTCL), graft vs host disease (GvHD) and bronchiolitis obliterans syndrome (BOS). They are also market leaders for producing extracorporeal photopheresis (ECP) devices. The Product A is an ECP device which uses a methoxsalen solution, currently marketed in the United States for CTCL. There are other pharmaceutical companies which manufacture similar products with similar mechanism of action for similar indications in various global markets. Company Z wants to understand the current market situation and the futuristic aspect for product A. It also wishes to understand the market scope and feasibility for expanding it product for other indications and other Ex-US markets. Competitive Intelligence is used here to provide key intel to Company Z which would help them to take the required strategic action so as to maintain their current position as a market leader and also expand their scope.

OBJECTIVE

The aim of this analysis is to explore the importance of Competitive Intelligence as an essential tool to help take strategic action for a business problem. The importance of CI and its tools will be better understood by taking a business question of Company Z regarding their Product A.

METHODOLOGY-

- **Study Design:** Descriptive study
- **Data collection method:** Secondary research
- **Sources of data collection:** Clinicaltrials.gov (for pipeline analysis), Company websites (for product details, industrial publications, investor reports, financials), SEC filings, LinkedIn (sales force estimation)
- **Keywords searched on Clinicaltrials.gov:** acute and chronic Graft vs Host disease, ECP devices, treatment and prophylaxis
- **Data cleaning steps:**
  - Once the keywords are entered, the search revealed 1235 studies
  - The entire clinical trials data was downloaded as .csv file
  - **Studies excluded:**
    - Based on study type– Expanded access, observational
    - Based on status– Suspended, Terminated, withdrawn and unknown status
    - Primary completion date– PCD before 2016 and blanks
    - Based on intervention-- Behavioral, diagnostic, dietary, imaging
    - Based on funder– All other (individuals, universities, organizations)
  - **Studies included:**
    - Based on study type– Interventional
    - Based on status– Active, not yet recruiting, recruiting, completed
    - Based on completion date– All post 2016
    - Based on intervention– procedure, drugs, others
    - Based on funder– Industrial and non-industrial
- **Total studies narrowed down were 106. Products plotted in pipeline are 72 (shown in following slides)**

To have an extensive market cover, we have tracked and observed all the competitors from various sources. This helps us to establish the future entries in a specific market; here in case the immunotherapy market which can pose a threat at the current market shares held under Product A.

CI as a tool is used here to answer the business question of analysing the position of Product A in the next ten years with respect to its market share and scope for expansion into global markets (Ex-US) as well as other indications (Apart from CTCL)

CI is an extensive procedure which requires inputs and inside information from the client Company Z, analytical reports from other consultancy firms as well as substantial secondary research by the organization providing the final intel supporting the SDM process.

Company Z has provided information regarding their existing product and indications in their website. They further informed their desire to explore GvHD as a potential indication for their product. Also, they have expressed their desire to expand their sales in Ex-US markets like Europe (EU), Canada (CA), Japan (JP) and others.

Company Z required various types of data compiled in various forms like consolidated information decks, monthly monitoring of competitive events and activity, latest news, conference, clinical trials, patents and trademarks, social media, financial and staff hiring patterns. Different 'trackers', as these monthly monitoring documents are called in CI, capture different types of data, each having their own significance and purpose.

Following were the sources that were used to track competitors of Product A of Company Z-

• Company's web pages for insights into target subjects or changes in strategy, product pricing, product benefits, and so on.

• Company news release for new product, staff, or expansion.

• Social media postings, particularly for new launches and estimating the social media buzz and presence.

• Job postings, since the kinds and number of open positions could indicate efforts to staff up for a replacement product or category development.

• Company information collectors like IMS.

• Social networks sites like LinkedIn and Facebook et al.

LITURATURE REVIEW

Functions of Competitive Intelligence

• Incorporates outer competitive and financial procedure into key strategy

• Generates pertinent bits of knowledge from research and organized analysis

• Enhances promotional activities, decision making, financial and operational accounts and tasks

• Conforms to antitrust and prized formula laws, legitimate and moral prescribed procedures and the customer's corporate code of conduct

• Minimizes decisive hazard and diminishes vulnerability about outside turns of events

Uses of Competitive Intelligence:

• Develop corporate or venture unit systems

• Shape counter-competitive systems against at least one contender

• Prepare a substitution item dispatch, new market passage, or other key move inside the market

• Benchmark different associations

• Anticipate and plan for future market openings and disturbances

• Assess viability of contenders showcase situating and stock informing

CI Methods:

- Competitive Strategy (Scenario Planning, War Gaming)
- Early Warning / Monitoring
- Research and Analysis
- CI Process Development + Consulting
- Win/Loss Analysis

Competitive Intelligence in Pharmaceutical Industry-

The worldwide pharmaceutical industry has been characterized for quite a while by its characteristic capacity to advance new things and organizations. Epic load from payers also as regulatory and assessing masters has been pushing down pharma associations' working edges. At an equivalent time, overall markets and patients anticipate progressively critical partition from

the associations. The continuous unsettling influences inside the buyer condition and patient fortifying build up an impression which will impact the very strategies that have described the business for quite a while.

Thusly, it is now, not sufficient to dispatch new things or organizations in business segments that are fast fixing off with generics and biosimilars. As patients despite everything become better taught and in this manner the enthusiasm for redid drugs goes up, pharma associations found the opportunity to move towards human administrations results rather than thing-based courses of action.

Key segments driving this move are:

 Downward weight on assessing by governments and back up plans is pushing pharma associations to show progressively essential impetus from their therapies1

 Payers are beginning to set up treatment shows and mentioning progressively essential straightforwardness around sedate esteeming

 Digitalization in the pharma region is permitting patients the opportunity to end up being logically attracted, instructed and empowered2

Despite these changes, pharma associations despite everything limit on standard strategies. At present, game plans for pharmaceutical associations are maintained their business community (strength/multi-distinguishing strength versus general prescription); treatment focus (exceptional ailment versus mass markets); business stage (clinical stage versus totally business); thing portfolio (checked versus generics); or land exertion (overall versus common, and so on.

Bits of information from Competitive Intelligence (CI) can help pharma associations recognize their middle characteristics inverse contenders. Such encounters can help associations with concentrating in on dismissed must change their commitments, yet their strategies as well. The examination of the serious condition also can control their Research and Development (R&D) focus.

Most pharma associations have quite recently got intricate CI limits that give steady bits of information on conditions and risks. Associations similarly can use inside knowledge to comprehend an evaluation of the affiliation itself, its R&D focus and business destinations. This

helps an association benchmark its presentation, perceive its characteristics and highlight need regions.

Superimposing results from business and serious understanding would in this manner have the option to help pharma associations find new streets to isolate their picture and fulfill a need inside the market.

To have a key clutch the market, it has become significant that the organization has the privilege and complete picture of the occasions happening all around and potential circumstances that may influence their future deals.

Competitive Intelligence has increased a lot of thankfulness and become a significant apparatus to satisfy the prerequisites, for example,

• Drug and gadget improvement

• Patient populaces

• Clinical preliminaries

• Drug and gadget licenses

• Market moving occasions

• Patient-based deals gauges

It encourages the pharmaceutical contenders to accomplish information, for example,

• Prioritize pharmaceutical R&D spend by discovering holes and neglected needs through the investigation of contenders' objectives and R&D needs

• Understand ailment the study of disease transmission and sickness sub-populaces focused in clinical turn of events

• Anticipate showcase changes through patent termination following

• Earmark who is entering or leaving your market through authorizing or procurement, likewise as who is making sure about or giving subsidizing

• Project income for your pipeline and promoted drugs

Following is a contextual investigation stressing on the utilization of Competitive Intelligence as a device for Product A by Company Z to break down the conceivable modern scene the medication may confront.

About Graft vs Host Disease (GvHD):

Graft-versus-host disease (GvHD) is an immune condition that occurs after transplant procedures when immune cells from the donor (known as the graft or graft cells) attack the recipient patient host's tissues; the disease is a side effect that is common after an allogeneic bone marrow transplant (stem cell transplant). An allogeneic transplant is one in which a patient receives bone marrow tissue or cells from a donor. Stem cell transplantation is a common treatment for many different cancers (malignancies), including cancers that affect the blood and lymph nodes, as well as some other (non-cancer) conditions that affect the blood or immune system. A stem cell transplant is sometimes performed after a relapse of leukemia or lymphoma that occurs after initial treatment. In addition to bone marrow transplant procedures, GvHD can also occur after transplantation of solid organs that may contain immune system cells such as white blood cells.

Tissues from healthy donors are checked prior to bone marrow transplant to see how closely matched they are to the host's own cells. When there is a close match in certain genetic markers, the risk of the disease is lower. The disease can range from mild to life-threatening in severity. There are two types of GvHD: acute or aGvHD and chronic or cGvHD.

The chance of developing GvHD is around 30%-40% when the donor and recipient are related and around 60%-80% when the donor and recipient are not related. The disease can affect many different organs in the body.

Immunosuppressant medications are the hallmark of treatment for GvHD. These include both corticosteroid drugs (such as prednisolone or methylprednisolone) and more advanced medications and techniques that reduce the immune response. Corticosteroids are the mainstay of therapy for GvHD, but other medications may be added or given when the GvHD does not respond well to steroid treatment. A number of different medications and combinations of medications are available to treat GvHD, and clinical trials are ongoing to examine new treatments as well as treatments for GvHD that does not respond to steroid treatment.

Some nonsteroid immune-suppressing drugs and treatments that have been used to treat GVHD include the following:

- ✓ Antithymocyte globulin (Thymoglobulin)
- ✓ Denileukin diftitox (Ontak)
- ✓ Daclizumab (Zenapax)
- ✓ Infliximab (Remicade)
- ✓ Sirolimus (Rapamune)
- ✓ Tacrolimus (Prograf)
- ✓ Mycophenolate mofetil (CellCept)
- ✓ Etanercept (Enbrel)
- ✓ Pentostatin (Nipent)
- ✓ Thalidomide (Thalomid)

Extracorporeal photophoresis (ECP) is a treatment that involves a combination of leukopheresis and photodynamic therapy, in which patient blood is exposed to a sensitizing agent followed by ultraviolet A irradiation and reinfused into the patient.

Some statistics on GvHD:

Incidence: Worldwide, the incidence of GvHD ranges from a low of 8x10^-7 per 100,000 persons to a high of 1.14x10-6 per 100,000 persons with an average incidence of 9.5x10-7 per 100,000 persons.[1] The reason for the low incidence worldwide is that the disease can only occur after a bone marrow transplantation, and bone marrow transplantations occur only in highly specialized centers.

In developing countries, the incidence of GvHD has not been studied, as bone marrow transplants are only performed in highly specialized centers.

In 2003, the incidence of GvHD was estimated to range from 4795 to 6850 total cases worldwide.[1]

Case Fatality Rate: The annual case fatality rate of GvHD is approximately 25%.[2]

Age: GvHD is more likely to occur in persons of older age. However, given that this is not a natural disease, but rather an iatrogenic disease, GvHD can occur at any age, depending on when a patient underwent a bone marrow transplant.

Gender: Males are more commonly affected with GvHD than females. The male to female ratio is approximately 1.4:1.[3]

Race: The prevalence of GvHD does not vary by race.

Global Market on GvHD treatment (Immunosuppressants): [1]

Introduction:

Graft versus host disease (GvHD) occurs following a donor stem cell transplant. GvHD is a frequent complication of bone marrow or stem cell transplantation using tissue from another person. Before transplantation, cells from possible donors are screened to understand how well donors' cells match with that of recipients. Stem cell transplantation is utilized to treat various diseases related to the blood. The procedure involves replacing diseased or damaged cells with healthy cells from a donor.

A donor's stem cells contain white blood cells (T cells) that help fight infections. Graft versus host disease occurs when these T cells attack the patient's own tissues, as the donated cells recognize the patient's body cells as foreign tissue. GvHD affects various parts of the patient's body. It most commonly affects the digestive system, liver, and skin. It is tough to predict who might develop graft versus host disease after a bone marrow or stem cell transplant. Chances of GvHD are reduced or symptoms are milder if the donor's cells match closely with that of the recipient's.

[3] Although allogeneic hematopoietic stem cell transplantation (HSCT) is a potentially curative treatment of hematologic diseases, GVHD is still a limiting factor for the outcome of these patients (35). With possible involvement of multiple organs such as the skin representing the most common appearance, GVHD in liver, gut and in rare cases in lung and neuromuscular system are reported. According to the Consensus of National Institute of Health further sub-classification can be done into acute and chronic GVHD (36, 37). Corticosteroids remain first-line therapy for both acute and chronic GVHD but due to its association with significant toxicity and an increasing number of patients developing steroid-refractory disease, many salvage therapies are currently available. Based on recently published literature, mammalian target of rapamycin (mTor)-inhibitors (Sirolimus), janus kinase (JAK)-inhibitors (Ruxolitinib), proteasome inhibitors (Bortezomib), and also interleukin (IL)-22 are showing promising efficacy

in the treatment of GVHD (38). For the treatment of chronic GVHD, Ibrutinib, an irreversible inhibitor of Bruton's tyrosine kinase (BTK), and Interleukin-2 inducible T-cell kinase (ITK), was recently granted FDA approval and is currently the only one approved for this purpose (39).

Key Drivers, Restraints, and Opportunities of Global Graft Versus Host Disease (GvHD) Treatment Market:

Graft versus host disease is a major cause of morbidity and mortality following stem cell transplants. Research findings suggest that even after treatments with intensive immunosuppressive therapy, 50% to 70% of patients transplanted from unrelated donors and 30% to 50% of patients transplanted from fully matched sibling donors develop some level of graft versus host disease. Presently, the global graft versus host disease treatment market is expanding, due to a rise in the prevalence and incidence of cancer patients. These patients are usually under chemotherapy.

The global graft versus host disease treatment market is also driven by bone marrow transplants surgeries performed globally for specific types of cancers. Rise in allogeneic type of stem cell transplants is expected to boost the graft versus host disease treatment market. However, costs related to authorization and clinical trials of treatment therapies for GvHD are expected to restrain the global graft versus host disease (GvHD) treatment market.

North America to Capture Major Share of Global Graft Versus Host Disease (GvHD) Treatment Market:

Based on region, the global graft versus host disease (GvHD) treatment market can be categorized into North America, Asia Pacific, Europe, Latin America, and Middle East & Africa. In terms of region, the graft versus host disease (GvHD) treatment market in North America and Asia Pacific is estimated to expand at a rapid rate due to a large incidence and prevalence rate of the global graft versus host disease. For instance, a research study suggests that around 30% to 50% of hematopoietic stem cell transplant (HSCT) recipients develop acute GVHD. That translates to 5500 patients/year who are likely to develop acute GVHD. Eventually, around 50% of patients with acute graft versus host disease have manifestations of chronic graft versus host disease.

The global graft versus host disease (GvHD) treatment market in Europe is also estimated to expand due to a rise in the geriatric population with cancer disease, improvements in medical research, and increase in clinical trials. The graft versus host disease (GvHD) treatment market in several regions is specifically driven by the adoption of advanced technologies in cancer treatment, increase in awareness about diseases, and rise in the number of chemotherapy treatments.

Key Players Operating in Global Graft Versus Host Disease (GvHD) Treatment Market:

The global graft versus host disease (GvHD) treatment market is highly fragmented, with the presence of various key players. Major Players operating in the global graft versus host disease (GvHD) treatment market are Novartis AG, Bristol-Myers Squibb, Pfizer, F. Hoffmann-La Roche, AbbVie, Merck & Co., Takeda Pharmaceutical, Abbott, Eli Lilly, Sanofi, Soligenix, Mesoblast Ltd, Johnson & Johnson Services, Inc., Mallinckrodt., ElsaLys Biotech SA, Incyte, Kadmon Holdings, Genzyme Corporation, etc.

About ECP Devices: [3]

Extracorporeal photopheresis (ECP) has been in clinical use for over three decades after receiving FDA approval for the palliative treatment of the Sézary Syndrome variant of cutaneous T-cell lymphoma (CTCL) in 1988. After the first positive experiences with CTCL, additional indications have been successfully explored including areas such as graft-vs.-host disease (GVHD), scleroderma, and solid organ transplantation. The mechanism of action is still not fully resolved, but important steps in understanding ECP in recent years have been very informative. Originally, the primary hypothesis stated that psoralen and ultraviolet A (UVA) in combination induce apoptosis in the treated immune cells. This view shifted in favor of dendritic cell initiation, modification of the cytokine profile and stimulation of several T-cell lineages, in particular regulatory T-cells. A number of ECP guidelines have been produced to optimize treatment regimens in the clinical context. ECP in the treatment of acute and chronic GVHD has shown promising results as second line therapy in steroid-refractory presentations. In solid organ transplantation, ECP has been used to increase tissue tolerance and decrease infections with opportunistic pathogens, attributed to the use of high doses of immunosuppressive medication. Infection with cytomegalovirus (CMV) remains a limiting factor affecting survival in solid organ

transplantation and the role of ECP will be discussed in this review. A trend toward prophylactic use of ECP can be observed and may further contribute to improve the outcome in many patients. To further deepen our knowledge of ECP and thus facilitate its use in patients that potentially benefit most from it, future prospective randomized trials are urgently needed in this rapidly growing field. The aim of this review is to (1) introduce the method, (2) give an overview where ECP has shown promising effects and has become an essential part of treatment protocols, and (3) to give recommendations on how to proceed in numerous indications.

ECP is a widely recommended treatment modality as a second-line treatment, particularly in steroid-refractory form of GVHD. Current recommendations indicate that treatment should be performed on 2 consecutive days every week or every 2 weeks until a response is noticeable. ECP Treatments should be continued for at least 8 cycles or until complete remission is occurring (40). In a retrospective multicenter analysis, ECP has shown response rates of 80% in acute and chronic GVHD patients (41). A meta-analysis reviewed 7 prospective studies on acute GVHD and found overall good response rates but also a necessity of further prospective controlled multicenter studies (42). In a recently published article, the use of ECP as an initial prophylactic treatment was discussed, indicating its beneficial effect (43). An uncontrolled, prospective trial was able to show promising results for prophylactic use which has still to be confirmed in future studies (44).

Global Market on GvHD treatment (ECP devices): [2]

Photopheresis Products Market to Reach US$9.99 Billion by 2024: Government Encouragement to Expedite Growth as Demand Rises

The Global Photopheresis Products Market appears to be highly consolidated, with the three leading players, Macopharma, Med Tech Solutions GmbH, and Mallinckrodt accounting for a whopping 95% of the market in 2015, finds Transparency Market Research (TMR). A number of leading firms have been directing their efforts toward the development of lighter, smaller, and more efficient devices. As a result, the level of competition between the leading market players is quite high.

According to the findings of TMR, the global market for photopheresis products was pegged at US$223.1 mn during 2015. Expanding at a promising CAGR of 5.9% between 2016 and 2014, the market is slated to achieve a revenue worth US$371.1 mn by the end of 2024. The closed systems segment represented a massive share of 81.1% in the global photopheresis products market. North America is slated to expand at a conducive CAGR of 5.8% during the forecast period.

Asia Pacific to Come into Prominence Driven by Increasing Transplantations

Based on geography, the global market for photopheresis products has been segmented into the Middle East and Africa, Asia Pacific, North America, Europe, and Latin America. The global market was dominated by North America during 2015, occupying almost 52% of the market in the same year. The growth in this region can be attributed to the favorable government policies for different diseases such as Cytotoxic T-cell (CTL), graft-versus-host disease (GVHD), and lung transplantations, which are treated by extracorporeal photopheresis (ECP) therapy.

However, Asia Pacific is waiting in the wings to displace North America in the forthcoming period. Asia Pacific held a mere 4% of the global photopheresis products market in 2015. Over the forecast period, the region will demonstrate significant advancement, expanding at a CAGR of 6.6% between 2016 and 2024, states TMR. The emergence of new photopheresis centers triggered by increasing transplantations, faster approvals of regulatory bodies, and growing adoption of these devices have been fueling the market in this region.

DATA COLLECTION AND INTERPRETATION

Based on the result obtained, we created the profile of Company Z and its competitors for Product A

Company Z- [5], [6]

Company Z Pharmaceuticals is a multibillion-dollar specialty pharmaceutical company focused on the mission: Managing Complexity. Improving Lives. They provide medicines to address unmet patient needs, stemming from 150 years of using their unique strengths, experience and expertise to help improve people's lives. It is an Irish–charge enlisted producer of strength pharmaceuticals (to be specific, adrenocorticotropic hormone), nonexclusive medications and imaging specialists. In 2017 it created 90% of deals from the U.S. medicinal services framework.

While Company Z is headquartered in Ireland for charge purposes, its operational home office are in the U.S. Organization Z's 2013 assessment reversal to Ireland drew debate when it was demonstrated Product A, was Medicaid's most costly medication.

Company Z gets (for repricing), fabricates, and circulates items utilized in demonstrative methodology and in the treatment of agony and related conditions. This incorporates the securing, assembling, and circulation of strength pharmaceuticals, dynamic pharmaceutical fixings, differentiate items, and radiopharmaceuticals. The organization utilized 5,500 and had net deals of $3.2 billion of every 2017; of which $2.9 billion was from the U.S. social insurance framework.

Organization Z has the following fundamental product offerings:

- Autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology
- Immunotherapy and neonatal respiratory critical care therapies
- Analgesics
- Gastrointestinal products

Product A by Company Z-

Product A (ECP device) is an immunomodulatory therapy that uses extracorporeal photopheresis (ECP) to help enhance immunologic response. It was first approved by the FDA in 1987 for the palliative treatment of CTCL skin symptoms in patients who were not responsive to other types of treatment.

Since launching over 30 years ago, there have been over 1 million treatments given. Product A is now available in more than 170 treatment centers across the United States. Treatment centers are independent, third-party facilities not owned, operated, or controlled by Company Z.

What is the potential competition (products of competitors) for Product A?

Following shows the potential and existing rivals in the US showcase.

It causes us to comprehend the potential contenders that would land in the market and decrease the portion of Product An in US.

The sources incorporate:

- US clinical preliminary stage (where all the progressing preliminaries are obligatory to enlist)

- Secondary research covering organization sites, showcase reports

CI landscape showing potential products in the pipeline of various companies for treatment of Acute GvHD:

Figure 1:

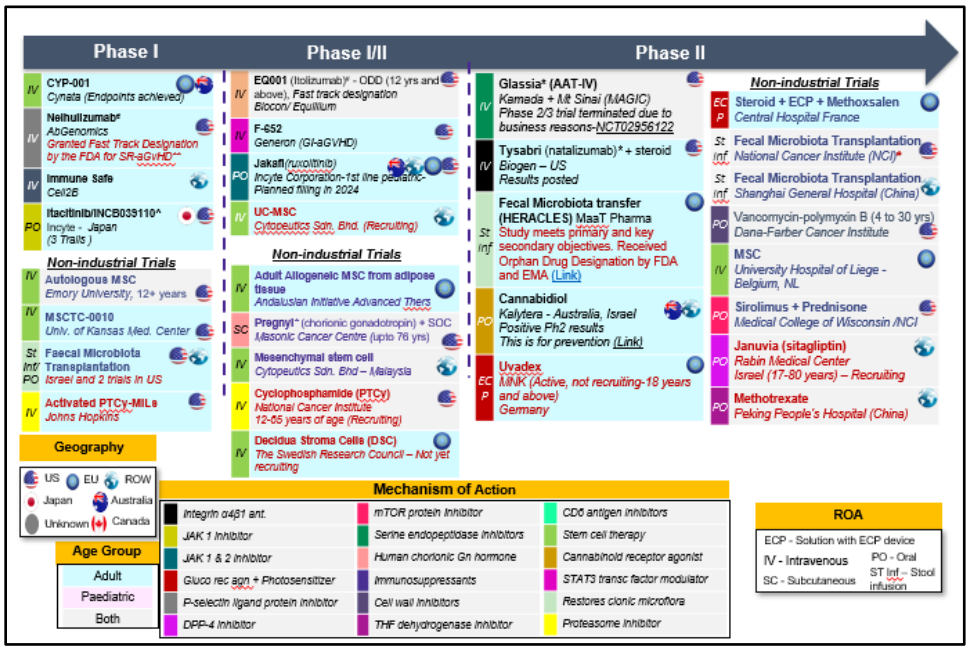
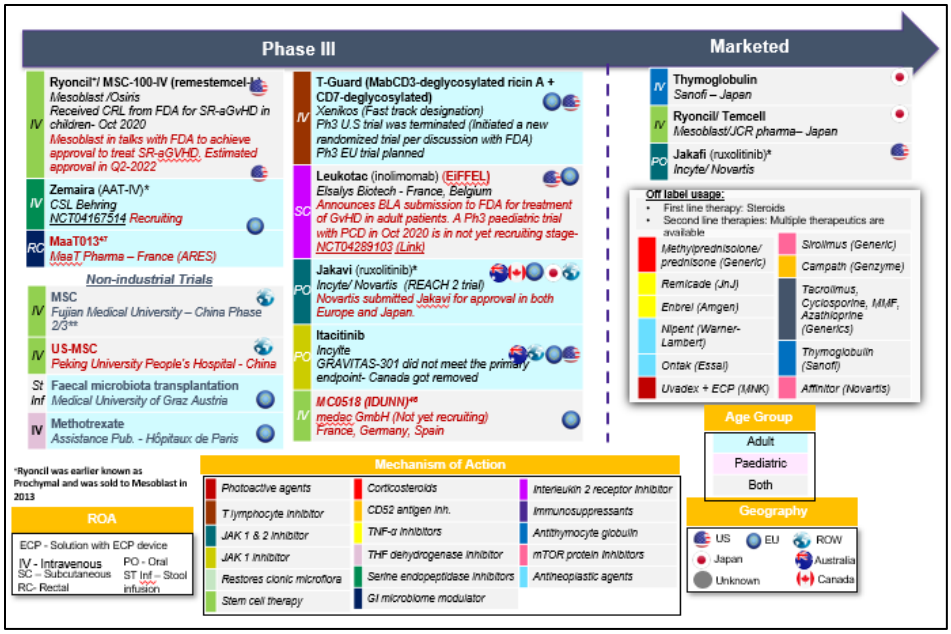
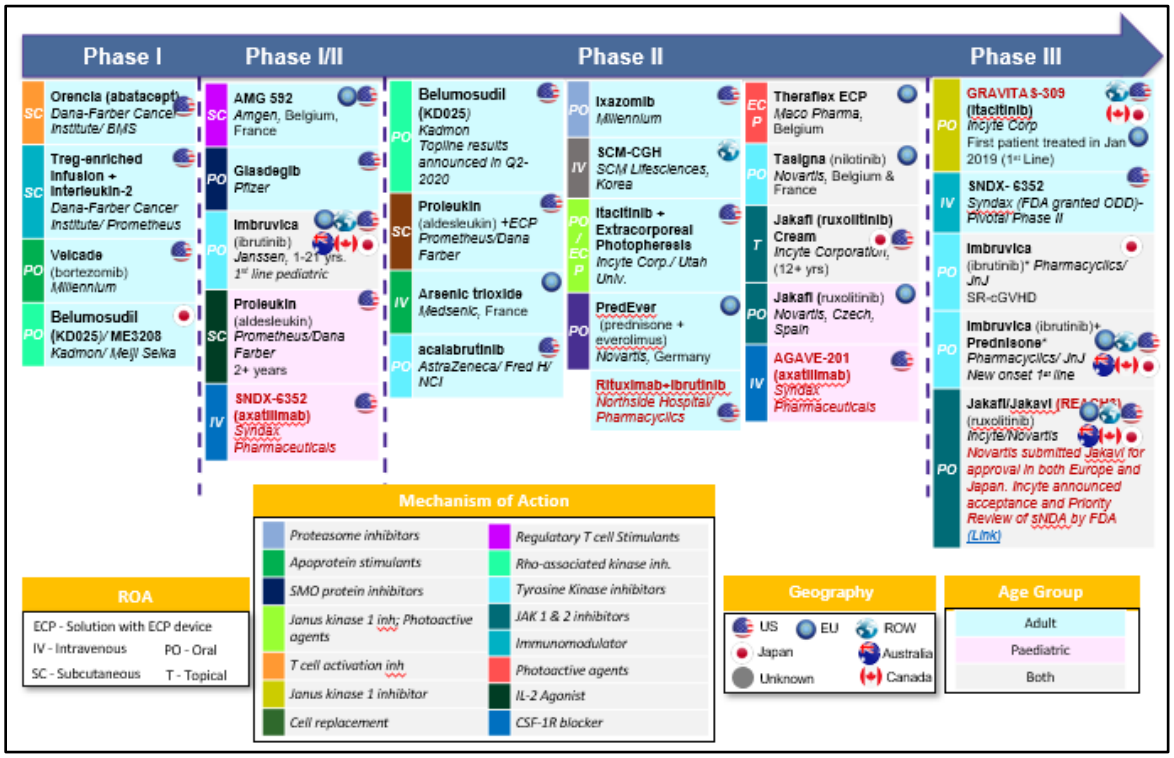


Figure 2:



CI landscape showing potential products in the pipeline of various companies for treatment of Chronic GvHD:

Figure 3:



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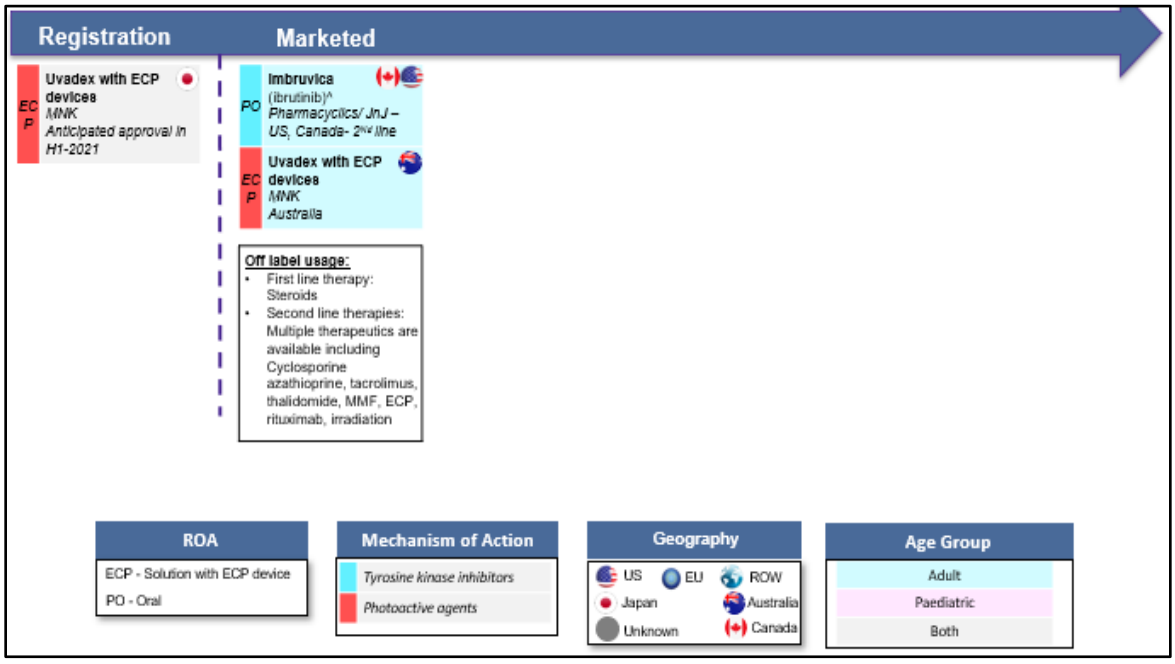
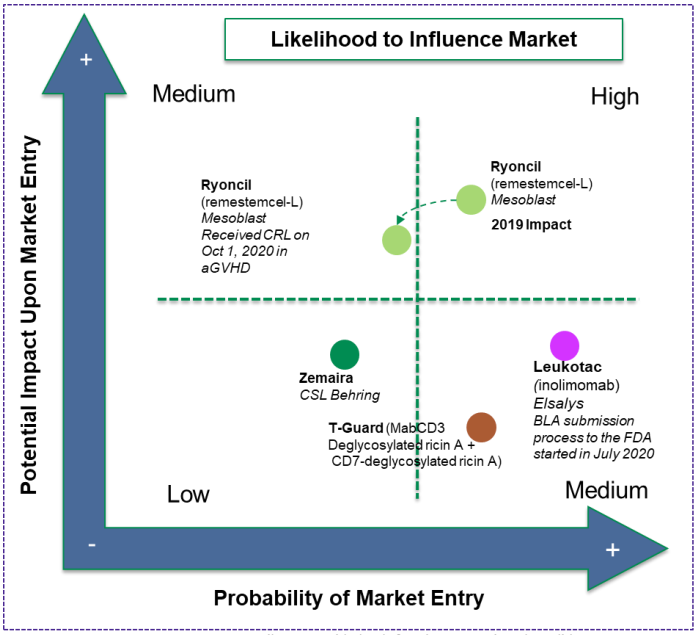


To have a better understanding for the futuristic expectations from the pipeline molecules, the impact of these potential competitors is analyzed by studying the strengths and weaknesses based

on the results of the trials, possible designations given by FDA and the probability of market entry.

Assessment of future impact to aGvHD treatment market:

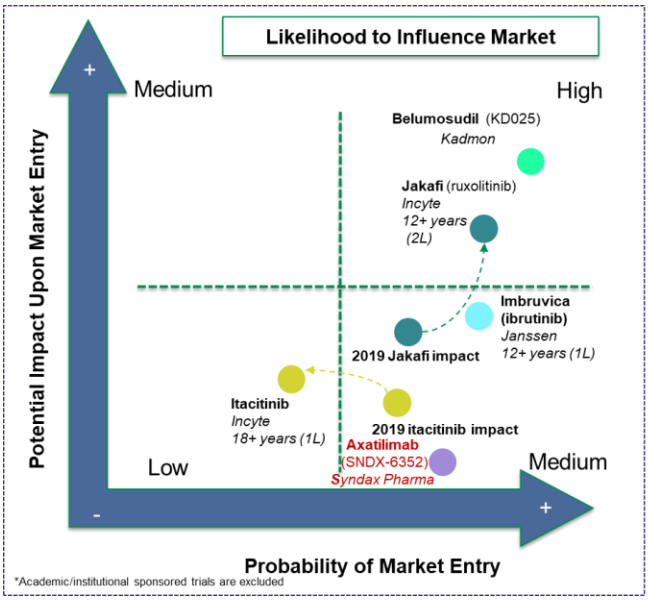
Figure 5:



Note: Details are provided only for phase 3 or pivotal candidates

Assessment of future impact to cGvHD treatment market:

Figure 6:



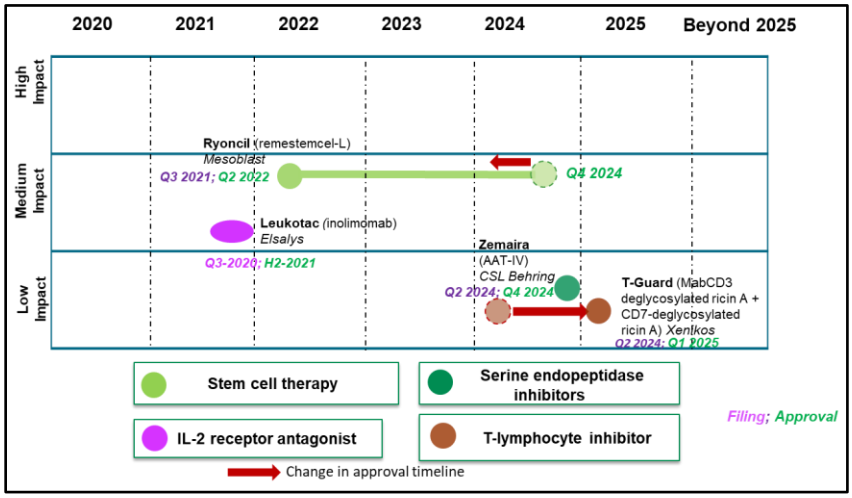
*Academic/institutional sponsored trials are excluded

We tried to analyse the probable entry of the potential competitors and plotted to have a comprehensive picture of the entire landscape. Each molecule is analysed based on its-

- Strengths and weaknesses-
- Results of the clinical trials conducted in the past
- Designations provided by FDA or EMA, enhancing the approval speed for the drug
- KOL's (Physicians, Pharmacists) point of view (part of the Primary Research Department)
- Treatable Patient pool number
- Planned promotional strategies
- Any strategic agreements or conference presentations
- Expected Sales force Unit
- Financial strengths of the company

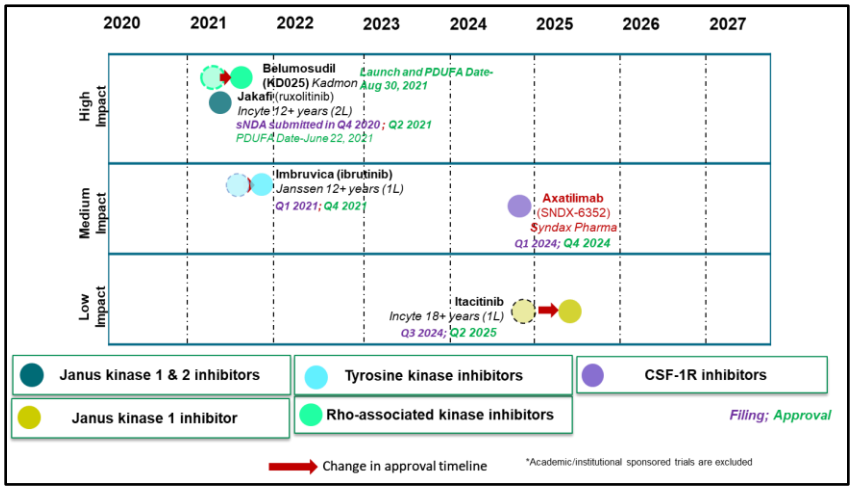
Potential Order of Entry for aGvHD Treatment Pipeline products:

Figure 7:



Potential Order of Entry for aGvHD Treatment Pipeline products:

Figure 8:



Cheat Sheet:

Cheat sheet provides a quick glimpse of the details of the product and its competitor products in terms of its manufacturer, mechanism of action, indications, current clinical trail phases and results, route of administration, frequency of dosage. It also includes latest news and regulatory affairs that favor launch (pros) and are against the benefit of the product/ company (cons).

Example cheat sheet created for aGVHD products in Phase 3 of pipeline:

Figure 9:

	Uvadex + ECP	Ryoncil / MSC-100-IV	Jakafi (ruxolitinib)
Sponsor	• **Mallinckrodt**	• **Mesoblast /Osiris/ Smith & Nephew**	• **Incyte Corporation/ Novartis**
MoA/ Type	• Photoactive agent	• Stem Cell Therapy	• Janus Kinase 1 and 2 inhibitor
Indication - Phase	• **Phase 3** - Grade B-C SR aGVHD (Pediatric and adult - 1 year to 21 years - NCT02194647)[3] **Trial terminated due to slow enrollment** • In Feb 2019, Mallinckrodt stopped patient enrollment as the interim response rate exceeded the specified target • Positive interim analysis results of Phase 3 trial were released in Feb 2019	• Positive data reported from two **Phase 3**- Grade B-D SR aGVHD (Pediatrics: 2 months to 17 yrs. - NCT02336230, follow up safety study - NCT02652130) • Filed with the FDA the first module of a rolling BLA submission in the treatment of aGVHD • The FDA issued a CRL to its BLA for remestemcel-L for the treatment of pediatric SR-aGVHD (Oct 2020)	• **Marketed** for treatment of aGVHD on May 2019 for SR-aGVHD in adult and paediatric patients aged 12 yrs and older • Phase 3 (REACH 2) trial- NCT02913261 • On Oct 16, 2019, Incyte announced that the REACH2 Pivotal Trial of Ruxolitinib (Jakafi®) Met Primary Endpoint in Patients with SR- aGVHD • Phase 2 (REACH 1)- NCT02953678
RoA	• Solution + Therakos Cellex device[5]	• IV[1]	• Orally twice daily
Frequency[10]	• 3 times a week for weeks 1-4 and 2 times a week for Weeks 5-12	• BID (2 x 10^6 MSC/kg) twice per week • for each of 4 consecutive weeks	• The starting dose of Jakafi is 5 mg given orally twice daily
Pros	• Approved in U.S. for **CTCL** • Approved in Australia for cGVHD and CTCL in Adults • Commonly used in **aGvHD** in pediatric and adults (off-label usage) • Adverse effects of ECP are minimal • Also in development for cGvHD, transplant and other autoimmune diseases • Positive interim data reported from ongoing Ph3 study: At the midway point (n=25) of the study, the ORR was 74% in patients who received four weeks of therapy. An ad hoc analysis at week 12 showed an ORR of 48%, allowing for the discontinuation of trial • Mallinckrodt and Terumo BCT announced that both the MSAC and PBAC recommended that UVADEX (Methoxsalen) for ECP with THERAKOS CELLEX be listed on the PBS in Australia for the t/t of CTCL in adults (July 2020)	• **Approved for aGvHD** in New Zealand, Canada and Japan • Has been used for the treatment of **SR aGVHD in children** in the U.S., Canada and several European countries under EAP • The FDA granted a **Fast Track and orphan designation** for the treatment of children with SR aGvHD • Phase 3 NCT02336230 data: Overall response at day 28 was 69% vs. 45% (p=0.0003). Overall survival at Day 100 was 75%. Survival at Day 100 for responders at Day 28 was 87% • Phase 3 NCT02652130 data: Day 180 OS 69% with 79% survival in day 28 responders • Mesoblast plans to meet with Office of Tissue and Advanced Therapies (OTAT) in Q3 2021 and is seeking a 6 month review timeline on re-submission • Earliest entry estimated to be in Q2-2022.	• **Approved** in U.S. for the treatment of SR-aGVHD in adults and paediatric patients aged 12 yrs and older • REACH1 study met its primary endpoint, demonstrating ORR of 55% (n=39/71) at Day 28. The best ORR was 73% (n=52/71). Most common treatment-emergent AEs - anemia (61%), thrombocytopenia (61%) and neutropenia (56%). • Phase 3 REACH2 trial met primary endpoint of improving overall response rate (ORR) at Day 28 with ruxolitinib treatment compared to best available therapy • PDUFA for Jakafi in SR- cGVHD on June 22, 2021
Cons	• Uvadex (8-MOP) targets both diseased and normal cells with no selectivity • Phase 3 trial terminated	• Company has poor stock performance in the past • Received CRL from FDA for pediatric SR-aGVHD • Mesoblast continues to be in discussion with the FDA to achieve approval	• Adverse events were seen in GvHD studies (previous retrospective data and real-life data) - Cytopenia, viral reactivation and infections

Figure 10:

	T-Guard (MabCD3	Itacitinib	Zemaira (AAT-IV)
Sponsor	**Xenikos**	**Incyte Corporation**	**CSL Behring**
MoA/ Type	**Destroys mature T- and NK cells**	Janus kinase 1 Inhibitor	Serine endopeptidase inhibitor
Indication - Phase	**Phase 1/2 - Netherland, Germany** *Study Completed in Nov 2016, Data presented at ASH 2017* NCT02027805 (Steroid resistant aGvHD Adults >= 18 yrs. Phase 3 registrational trial **terminated**- NCT04128319 (Initiated a new randomized trial per discussion with FDA)	**Phase 3 –Global Recruiting** NCT03139604 GRAVITAS-301: Failed to meet the primary endpoint in phase 3 aGVHD study **Pediatric Study :** **Phase 1/2 - U.S., EU Not yet recruiting** NCT03721965 (The study was **terminated** due to lack of efficacy in a separate phase III study) *Grade B-D, Steroid-naïve 1st-line aGvHD*, **Phase 2 by Icahn School of Medicine at Mount Sinai,** U.S .Recruiting NCT03846479	**Phase 3 started in Jan 2020 with PCD in Nov 2023** (Adult >= 18 yrs NCT04116254 – U.S.) **Phase 2/3 ongoing:** NCT03805763 (GVHD prevention)- U.S, EU, ROW Study started in Dec 2019 (MODULAATE trial) **Phase 2 completed:** NCT01700556 (adults- 18yrs and older)- Conducted by CSL Behring and University of Michigan Rogel Cancer Center
RoA	IV	Oral Tablet	IV
Frequency	-	**200mg or 300 mg QD**	lyophilized powder for IV
Pros	• Plans to Initiate pivotal Trial in EU • IND application got cleared • A pivotal Phase 3 trial in the U.S and Europe is expected to commence in the second half of 2021.[15]	• In a proof-of-concept phase 1 trial (NCT02614612) for Itacitinib plus steroids in aGVHD - Overall response in first-line population (83%, 10/12 pts) was superior than in steroid-refractory setting (65%, 11/17pts) • In Ph3 GRAVITAS study: o The primary endpoint of improving overall response rate (ORR) at Day 28 compared to placebo plus corticosteroids was 74.0 percent vs. 66.4 percent, p=0.08, respectively (difference was not statistically significant) o The most common adverse events were thrombocytopenia (34.9 percent for itacitinib and 34.7 percent for placebo) and anemia (29.8 percent for itacitinib and 25.0 percent for placebo)	• Phase 2 NCT01700556 study was completed in Oct 2018 with results posted • 65% of the patients responded to Zemaira at the dose of 60mg/kg (primary outcome) and 35% of the pts achieved a complete response to treatment • **Approved in the U.S. and EU for Alpha 1-antitrypsin deficiency**
Cons	• Clinical stage developmental company • Terminated Phase 3 registrational study in U.S.	• First line treatment vs. **2nd line off-label usage of Uvadex** • **Data from the Phase 3 GRAVITAS-301 study:** o Itacitinib in combination with corticosteroids **did not statistically improve overall response rate or non-relapse mortality compared to placebo plus corticosteroids**	• Phase 2 GvHD treatment data: Infectious mortality was 10% at 6 months and 2.5% within 30 days of last AAT infusion

Monthly Monitoring:

The above-mentioned CI tools are updated on a quarterly, half-yearly or annual basis. However, certain other tools track business intelligence on a monthly basis. These tools are called trackers. There are seven types of trackers which we used for this particular client. Each tracker describes a unique set of detail which provides different intel about the competition. The first is a News tracker. As the name suggests, the news, press releases and publications of the competitive companies are tracked in this section. Hiring tracker helps assess the job openings (can be filtered for job description, geography, position, role etc) and the sales force estimate. Activity and Social media trackers help monitor the earning call announcement dates, conferences planned/attended, workshops or any other important events that the competitor companies may attend and also the social media buzz around it. Financial tracker helps track the revenue, net sales, assets and liabilities, and the R&D expenses by the companies. Patent and Clinical trackers help keep record of the kind of patents that companies apply for and the clinical trials ongoing along with their phases, geography, expected launch time estimation and other nuances of their launch in the market.

CONCLUSION

The way to serious knowledge is that subsequent word – insight. Data accumulated anyway officially or casually will not help an organization except if it is investigated astutely or cautiously. At exactly that point can the data educate key or different choices in the association.

Different types of data gathered and consolidated in various forms can be used to interpret various results. The companies can harness the data to form their future operational strategies and make business decisions accordingly. These secondary and primary intel facilitate the SDM process of the business.

CI is a business work that works close by other hierarchical offices to lead essential and optional exploration. The most significant piece of CI is guaranteeing that the information gathered is exact and important to partners. Guaranteeing precise and significant information assortment requires serious knowledge projects to offer an assortment of administrations. These administrations permit CI projects to gather, examine, and disperse information that address the novel needs of an association, office, and group. Therefore CI frames a significant branch for the organization that encourages them with key intel.

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