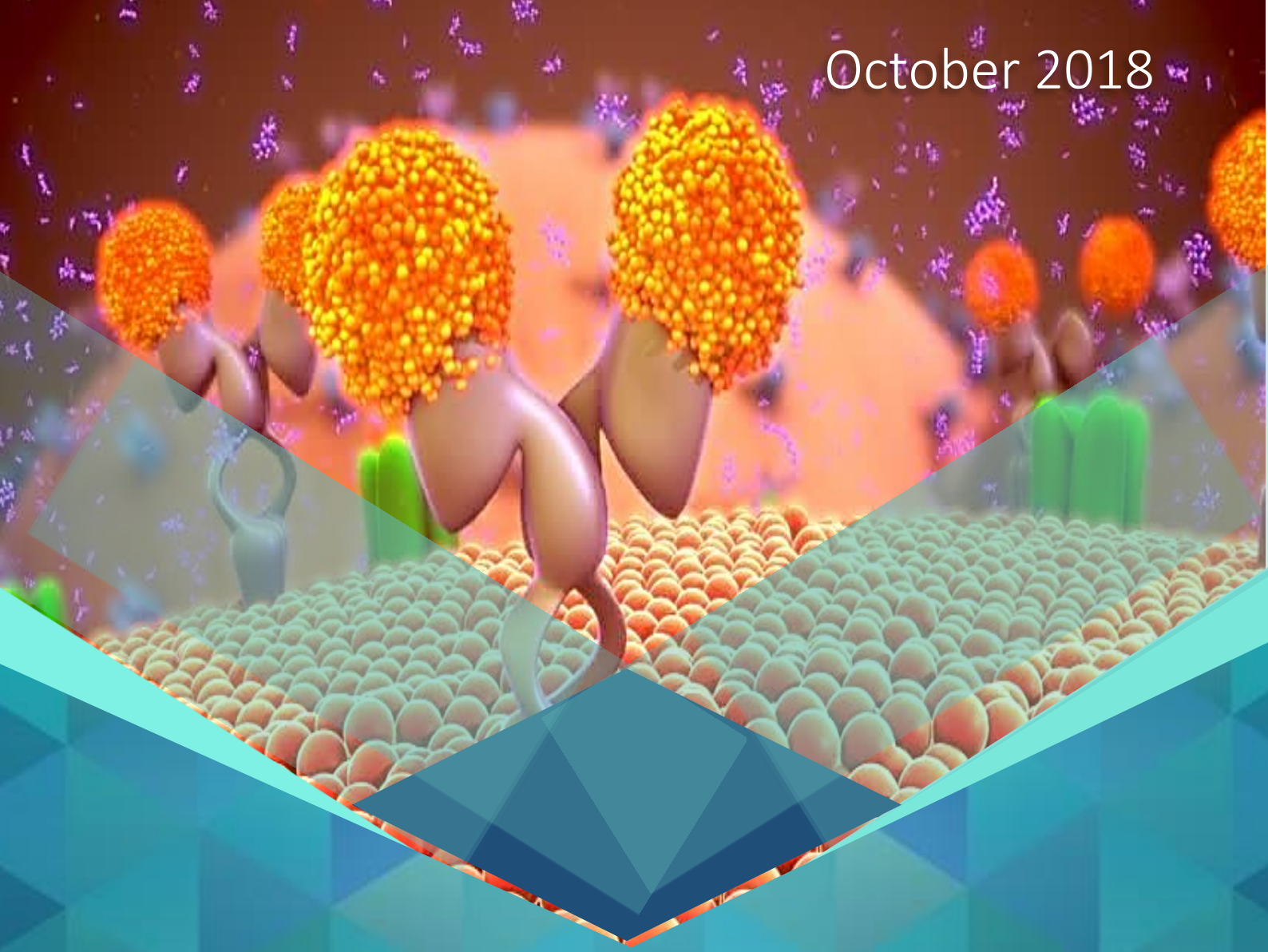
October 2018



Anti-CD37 Antibody

Pipeline Insight

Report Introduction

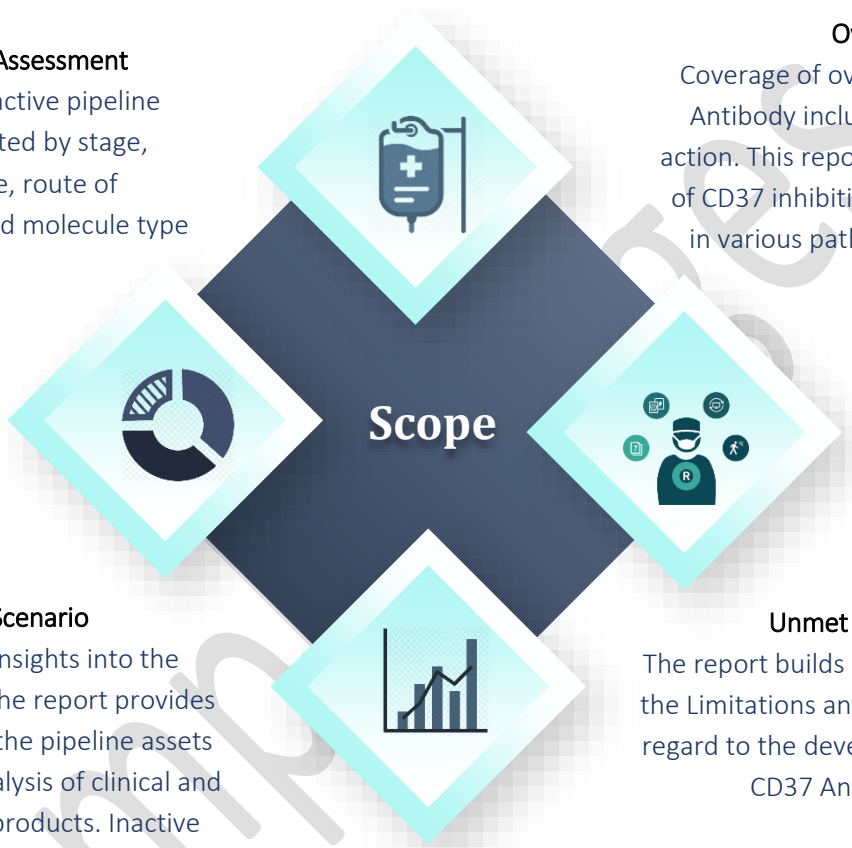
"Anti-CD37 Antibody- Pipeline Insight, 2018", report provides comprehensive insights about pipeline drugs based in Anti-CD37 Antibody Pipeline. It covers the pipeline drug profiles including clinical and non-clinical stage products. It also provides therapeutics assessment by product type, stage, route of administration and molecule type. It further highlights the inactive pipeline products in this space.

Therapeutic Assessment

Assessment of active pipeline assets segmented by stage, product type, route of administration, and molecule type

Overview

Coverage of overview of Anti-CD37 Antibody including mechanism of action. This report also covers the role of CD37 inhibition and its expression in various pathological conditions



Pipeline Scenario

Comprehensive insights into the pipeline products. The report provides detailed profiles of the pipeline assets and comparative analysis of clinical and non-clinical stage products. Inactive products are also part of the report

Unmet Needs

The report builds understanding of the Limitations and challenges with regard to the development of Anti-CD37 Antibodies

Secondary sources information and data has been collected from various printable and non-printable sources like search engines, News websites, Government Websites, Trade Journals, White papers, Magazines, Trade associations, Books, Industry Portals, Industry Associations and access to available databases.

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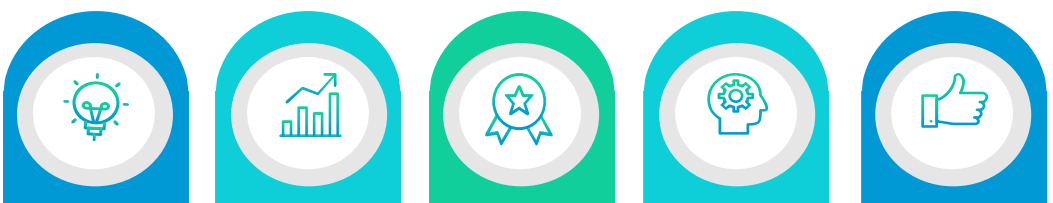

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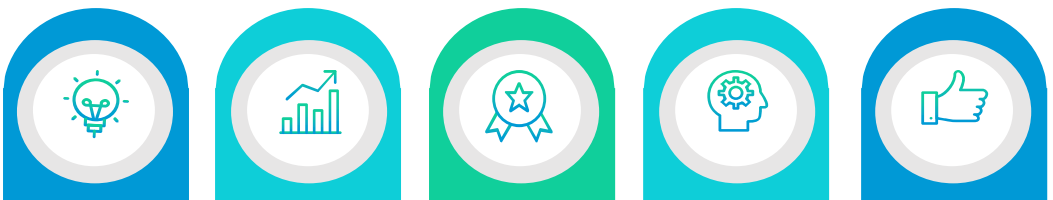
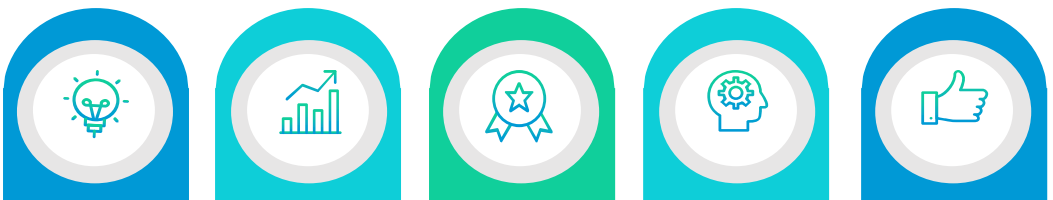


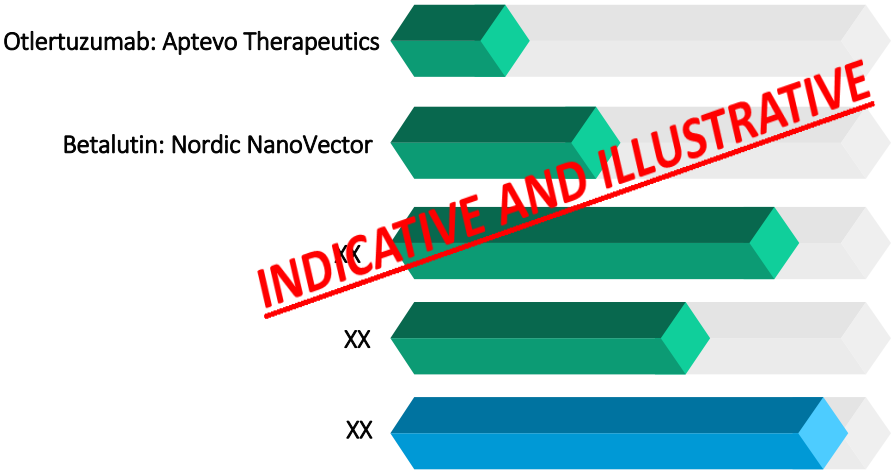
Overview

The CD37 antigen is a transmembrane protein of the tetraspanin superfamily that is highly expressed on B cells during the pre-B to peripheral mature B-cell stages, but is absent on early progenitor cells or terminally differentiated plasma cells. In normal tissues, CD37 expression is restricted to lymphoid tissues. However, CD37 is highly expressed on malignant B cells in non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL). This expression profile suggests that CD37 represents a promising therapeutic target for B-cell malignancies.

Further information in detailed report…..

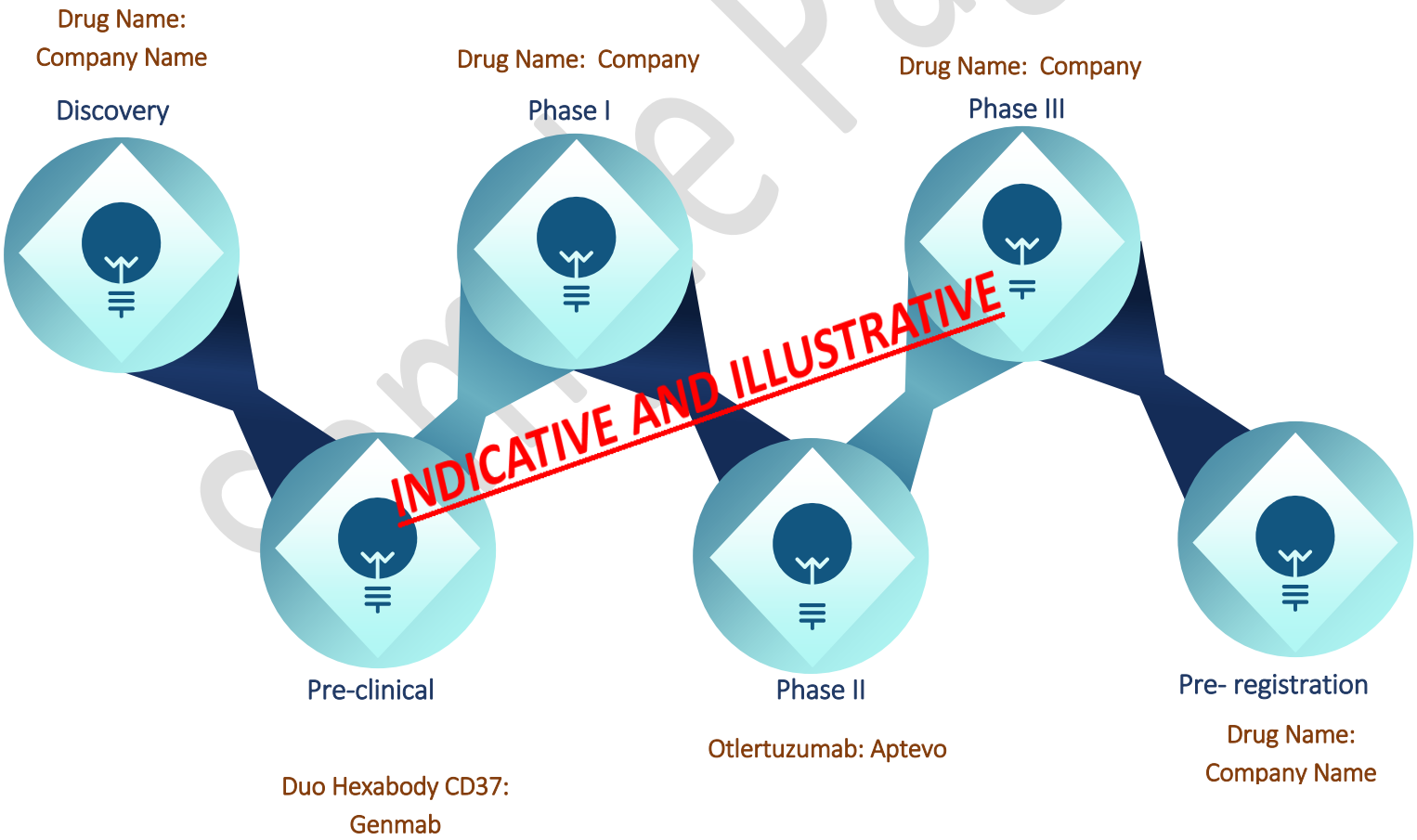


Pipeline Therapeutics



- Some of the key players include **Aptevo Therapeutics** which is developing **Otlertuzumab** in Phase II stage
- **Genmab** is developing a Pre-clinical candidate **Duo Hexabody CD37**

Comparative Analysis



Sample Profile

Otlertuzumab: Aptevo Therapeutics

Product Description

Otlertuzumab (also referred as TRU-016) is being developed by Aptevo Therapeutics (a spinoff from Emergent Bio Solutions). The drug candidate is in phase II stage of development for the treatment of Chronic Lymphocytic Leukemia (CLL) and is in the Phase I stage of clinical development for Peripheral T cell Lymphoma.

Otlertuzumab is a humanized monoclonal antibody based on Aptevo's ADAPTIR modular protein therapeutic platform. It targets CD37, a cell surface protein that is expressed on the surface of normal and transformed B cells, and also recently discovered to be present on the surface of T-cell lymphomas. It mediates the death of CD37-expressing cells by various mechanisms **including direct cell death**, **antibody-dependent cell-mediated cytotoxicity (ADCC)**, and **phagocytosis**. Otlertuzumab has previously been studied in a randomized Phase II study which demonstrated the efficacy and tolerability of otlertuzumab, combined with bendamustine, in relapsed chronic lymphocytic lymphoma (CLL).

The drug candidate was initially developed by Trubion Pharmaceuticals, however Emergent Biosolutions acquired Trubion Pharmaceuticals in August 2010. In August 2016, Aptevo Therapeutics completed its Separation from Emergent BioSolutions and started operating as an independent, corporation.

Further information in detailed report.....

Research and Development

Clinical Studies

Phase Ib/II

NCT01188681: In September 2010, Aptevo Therapeutics initiated a Phase Ib/II Open Label Study to Evaluate the Safety and Efficacy of TRU-016 in combination with Bendamustine vs. Bendamustine alone in patients with relapsed Chronic Lymphocytic Leukemia. This study consisted of two parts. The initial dose escalation stage was a Phase Ib study evaluating the safety and tolerability of two doses of TRU-016 administered in combination with bendamustine to patients with relapsed chronic lymphocytic leukemia (CLL). In the randomized Phase 2 stage of the study, the efficacy and safety of the selected dose of 20 mg/kg TRU-016 combined with bendamustine was compared to bendamustine alone. The pharmacokinetics and pharmacodynamics of TRU-016 and the development of antibodies to TRU-016 were evaluated in both phases of the study. The primary aim was to evaluate the response per International workshop on Chronic Lymphocytic Leukemia (IWCLL) and secondary aim was to evaluate Overall response rate per National Cancer Institute. This Phase Ib/II trial targeted to enroll 79 participants and has been completed in December 2014.

Results:

According to the Phase Ib/II results published by the Company, total 65 patients were treated in this study (including 32 with otlertuzumab and bendamustine and 33 with bendamustine alone). The following outcomes have been reported-

- The combination of otlertuzumab and bendamustine was well tolerated and significantly increased the response rate (69% vs. 39%, P=0.003) and prolonged the progression-free survival rate (15.9 months vs. 10.1 months, P=0.0059) over single-agent bendamustine treatment
- The overall incidence of adverse effects was similar between the two treatment cohorts, with a reported higher incidence of pyrexia, neutropenia, and thrombocytopenia with the combination. However, the addition of otlertuzumab did not appear to increase the number of serious adverse events.

Further information in detailed report.....

Phase I

NCT01644253: In September 2012, Aptevo Therapeutics initiated Phase Ib, open label study to evaluate safety and efficacy of TRU-016 in combination with Rituximab, Obinutuzumab, Rituximab and Idelalisib, or Ibrutinib in Chronic Lymphocytic Leukemia and with Bendamustine in Peripheral T-cell Lymphoma. This Phase Ib trial intends to enroll 123 participants and is expected to be completed in December 2019 with an estimated primary completion in June 2019.

Further information in detailed report.....

Clinical Trials Description

Phase	Intervention	Indication	Trial Identifier	Status
Phase I b/II	Otlertuzumab; Bendamustine	Chronic Lymphocytic Leukemia (CLL)	NCT01188187	Completed
Phase I	Otlertuzumab; rituximab; obinutuzumab; idelalisib ; ibrutinib	Chronic Lymphocytic Leukemia; Peripheral T-cell Lymphoma	NCT01644253	Recruiting
Phase I	Otlertuzumab	Chronic Lymphocytic Leukemia (CLL); Non-Hodgkin's Lymphoma (NHL)	NCT00614042	Completed
Phase I	Otlertuzumab; bendamustine; rituximab	B-cell Small Lymphocytic Lymphoma Recurrent	NCT01317901	Completed

Further information in detailed report.....

Otlertuzumab

General Description	
Drug Name	Otlertuzumab
Generic Name	otlertuzumab
Alias Name	TRU-016; TRU016; TRU 016
Company	Aptevo Therapeutics
Product Type	Mono
Therapy Area	Oncology
Indications	Chronic Lymphocytic Leukemia ; Peripheral T cell Lymphoma
Highest Stage of Development	Phase Ib/II
Designation	NA
Licensed From	Trubion Pharmaceuticals
Licensing Type	Worldwide
Development Partner	NA
Institutional Partner	NA
Route of Administration	Intravenous
Target	CD37
Mechanism of Action	CD37 inhibitor Monoclonal Antibody
Technology	Aptevo's ADAPTIR modular protein therapeutic platform
Molecule Type	Monoclonal antibody
Drug Origin	Human Source
Chemical Name	NA
Chemical Formula	NA
Molecular Weight	NA
CAS Registration No.	1372645-37-8
ATC Classification	L01XC (Monoclonal Antibodies)

Therapeutic Assessment: Active Products

Assessment by Product Type

Figure 1: Assessment by Product Type

Table 1: **Assessment by Product Type**

Product Type	Number of Products

Assessment by Stage and Product Type

Figure 2: Assessment by Stage and Product Type

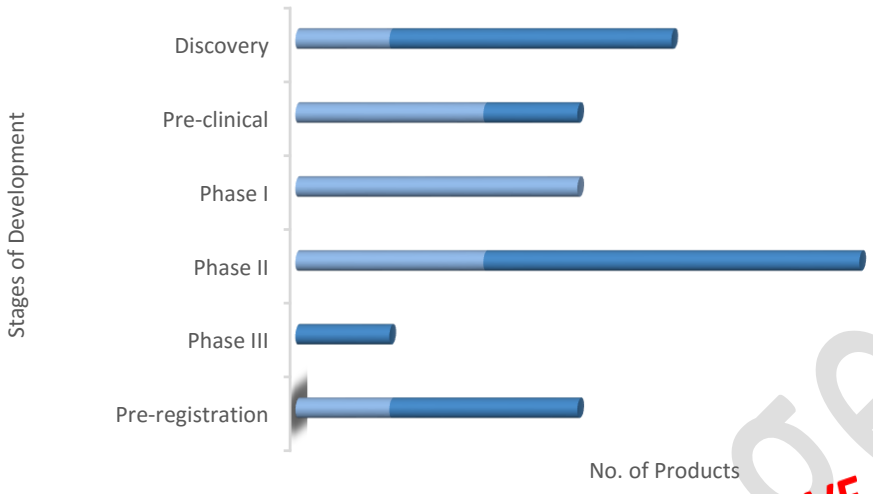


Table 2: **Assessment by Stage and Product Type**

Product Type	Stage of Development	Number of Products

Assessment by Route of Administration

Figure 3: Assessment by Route of Administration

Table 3: **Assessment by Route of Administration**

Route of Administration	Number of Products

Assessment by Stage and Route of Administration

Figure 4: Assessment by Stage and Route of Administration

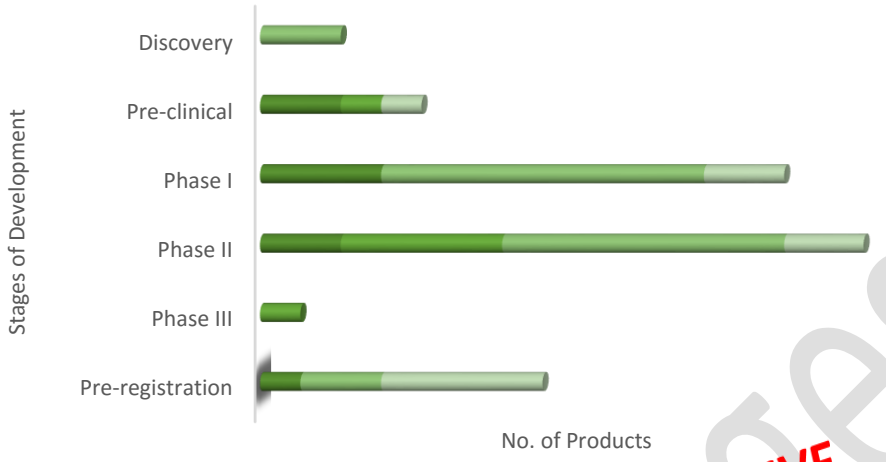


Table 4: **Assessment by Stage and Route of Administration**

Route of Administration	Stage of Development	Number of Products

Assessment by Molecule Type

Figure 5: Assessment by Molecule Type

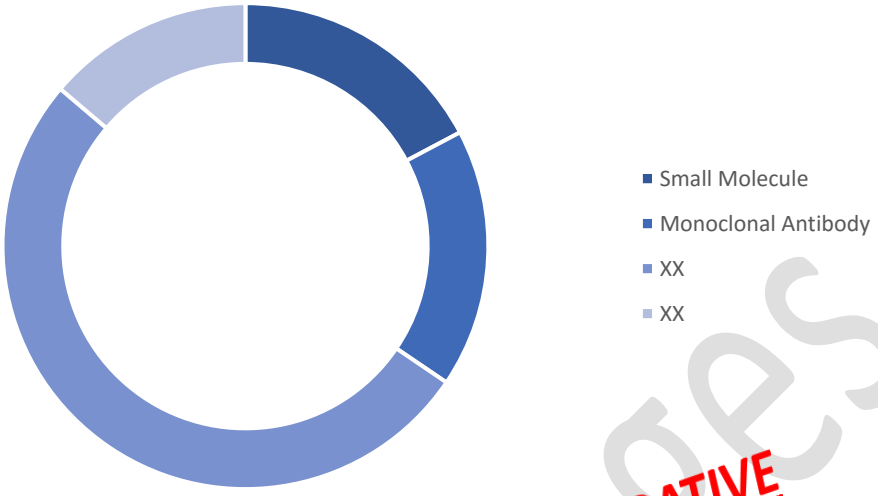


Table 5: **Assessment by Molecule Type**

Molecule Type	Number of Products

Assessment by Stage and Molecule Type

Figure 6: Assessment by Stage and Molecule Type

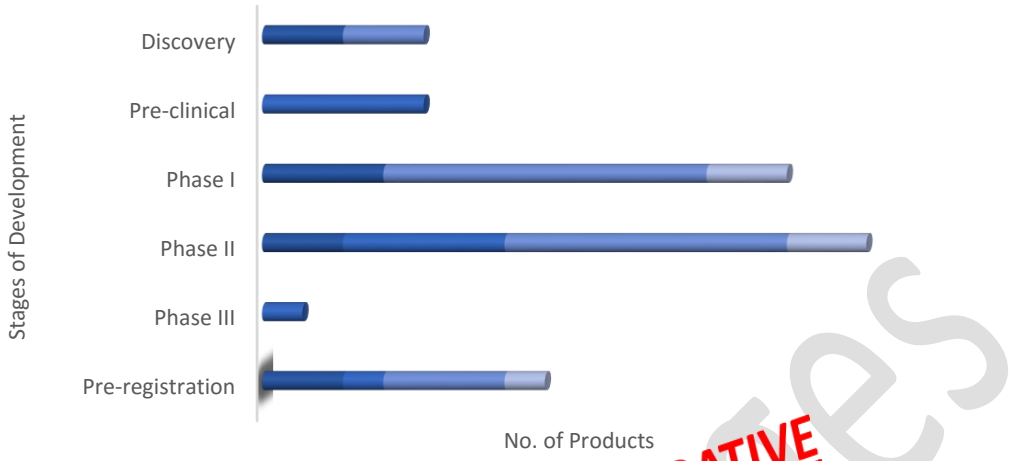


Table 6: **Assessment by Stage and Molecule Type**

Molecule Type	Stage of Development	Number of Products