

FOCUS

Development and future commercialization of cell-based immunotherapy products for treatment of blood cancers and inherited blood disorders.

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Kiadis is proud to be a partner of The Leukemia and Lymphoma Society and the Thalassemia International Federation.



ABOUT KIADIS PHARMA

Kiadis Pharma is a clinical stage biopharmaceutical company focused on research, development and future commercialization of innovative cell-based immunotherapy products that provide for a safer and more efficacious treatment of blood cancers and inherited blood disorders, improving survival and quality of life and addressing significant unmet medical needs.

The Company believes that its products address current risks and limitations of allogeneic hematopoietic stem cell transplantation (HSCT). HSCT is considered the most effective curative approach to blood cancers and certain inherited blood disorders and Kiadis Pharma expects that HSCT will become a treatment option for many more patients once current risks and limitations are addressed.

PRODUCTS IN DEVELOPMENT

ATIR™ (Allodepleted T-cell Immunotherapy) is an innovative cell-based therapeutic that addresses the key risks and limitations of current HSCT treatments in blood cancers and inherited blood disorders, being opportunistic infections, Graft-versus-Host Disease (GVHD), cancer relapse and limited donor availability.

Using Kiadis Pharma's Theralux platform, those T-cells that attack the patient, causing GVHD, are eliminated. At the same time, the full immune repertoire of other donor immune cells, including immunological memory, is retained in the final product to fight infections. ATIR101 also contains T-cells from the donor that could eliminate residual cancer cells reducing the risk of return of the disease, which is called the graft-versus-leukemia (GVL) effect.

After an HSCT treatment, patients are highly susceptible and vulnerable to infections. Immune cells in ATIR™ will help fight these opportunistic infections and bridge the time until the immune system has fully re-grown from stem cells in the transplanted graft.

ATIR™ products (see development status below) are cellular products for infusion which consist of donor lymphocytes (immune cells) specifically manufactured for each individual patient from a healthy, haploidentical family member's donation.

ATIR™ provides patients with fully functional T-cells from a partially matched family donor. ATIR™ is designed to reduce relapse rates and death from infections while not eliciting severe acute GVHD. ATIR™ is and adjunctive immune-therapeutic to HSCT.

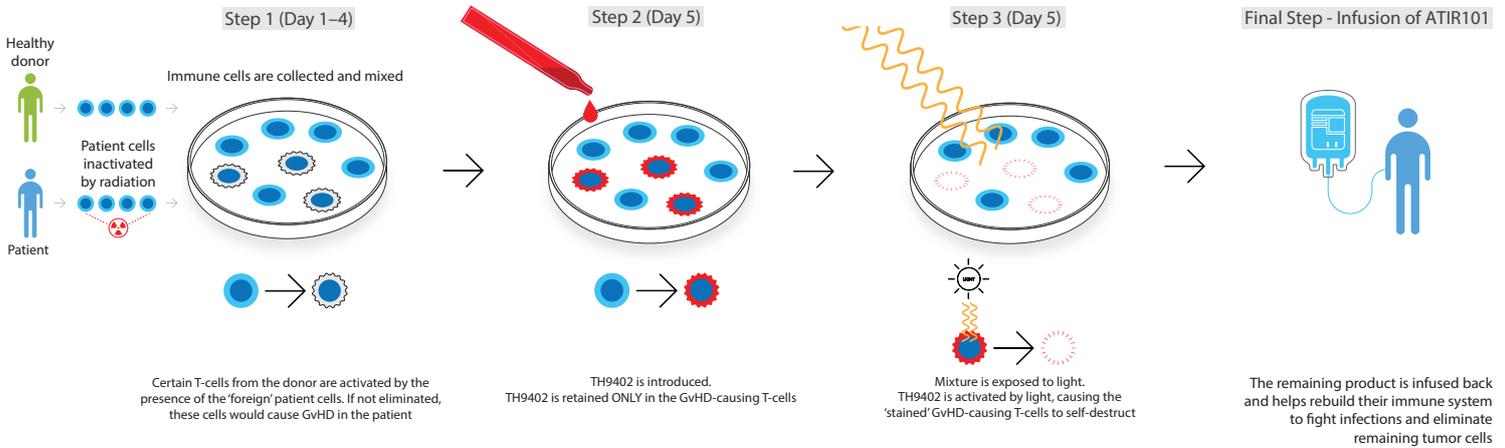
Products	Claim / Indication	Phase I	Phase II	Phase III
ATIR101	Providing T-cell based immune-protection reducing relapse rates and death from infections after HSCT in blood cancer patients			
ATIR201	Providing T-cell based immune-protection after curative-intent HSCT in Thalassemia patients			

 Current status  H1 2017 (Expected)

CLINICAL DEVELOPMENT

- Phase I/II dose escalation trial demonstrated that ATIR101 can be safely administered up to high doses without causing severe acute GVHD
- Positive data from the international Phase II clinical trial (NCT01794299) were presented in December 2016 at the Annual Meeting and Exposition of the American Society of Hematology (ASH), supporting the safety profile and showing efficacy of ATIR101 in patients who could not find a matching donor in time.
- Enrollment is ongoing in a further Phase II clinical trial with ATIR101 to assess the safety and efficacy of using a second dose of ATIR101
- ATIR101 has been awarded Orphan Drug Designations in the US and Europe

ATIR™ MANUFACTURING PROCESS



MANUFACTURING

Kiadis Pharma has established a GMP-compliant, manufacturing process that has been successfully transferred to three GMP-manufacturing sites in North America and Europe. The Company is one of seven companies to have ever been issued an Advanced Therapy Medicinal Product (ATMP) certificate for manufacturing quality and non-clinical data by the European Medicines Agency (EMA).

MARKET POTENTIAL

ATIR101 has the potential of providing life-saving products to ~19,000 blood cancer patients a year, with a substantial expanding primary market and complementary product trends. The Company estimates that approximately 35% of patients who are eligible for, and who are in urgent need of, HSCT will not find a matching donor in time. A partially matched (haploidentical) family donor, however, will be available to over 95%. Recent developments in cell-based immunotherapy have resulted in approaches which may allow more patients with blood cancers to go into remission, including various CAR-T approaches. These patients will then be eligible for curative HSCT. The product may benefit from market exclusivity up to 10 years post launch in the EU and 7 years in the US due to its orphan drug status.

ATIR101 AIMS TO ADDRESS THE RISKS AND LIMITATIONS OF HSCT

Current sequence of options physicians will consider →

	Haploidentical donor + ATIR101	Identical Sibling (SIB)	Matched Unrelated (MUD)	Haploidentical donor + Cyclophosphamide*	Umbilical Cord Blood (UCB)
Time to collect stem cells	< 1 month	< 1-2 months	3-6 months	< 1 month	2-3 months
Donor availability	>95%	≤ 25%	45-55%	>95%	Limited
Risk of life-threatening GVHD	Low	Low	Moderate - High	Moderate - High	Moderate
Need for immune suppressants	No	Yes	Yes	Yes	Yes
Risk of opportunistic infections	Low	Moderate	Moderate	Moderate - High	High
Risk of relapse in leukemia	Low	High	Moderate - High	High	High

* Often referred to as the Baltimore protocol. Treatment method was established at the John Hopkins Hospital, Baltimore, USA. (Luznik et al., Biol Blood Marrow Transplant. 2008)

Source table: Company information, CIBMTR, 2014 and Defined Health, 2013 commissioned by the Company. Survey included 50 US and 50 EU physicians.