

# **Astellas and Adaptimmune Enter into Agreement to Co-Develop and Co-Commercialize Stem-Cell Derived Allogeneic CAR-T and TCR T-Cell Therapies**

- Agreement covers the co-development and co-commercialization of up to three T-cell therapies -
- Agreement leverages Astellas' Universal Donor Cell Platform and Adaptimmune's stem-cell derived allogeneic T-cell platform -
- Astellas will pay Adaptimmune an upfront payment, research funding, development and commercial milestones, and royalties on net sales on co-commercialized products -

TOKYO, PHILADELPHIA and OXFORDSHIRE, United Kingdom, Jan. 14, 2020 (GLOBE NEWSWIRE) -- Astellas Pharma Inc. (TSE: 4503, President and CEO: Kenji Yasukawa, Ph.D., "Astellas"), through its wholly-owned subsidiary Universal Cells, Inc, and Adaptimmune Therapeutics plc (Nasdaq:ADAP), a leader in cell therapy to treat cancer, announced that they have entered into a co-development and co-commercialization agreement to bring new stem-cell derived allogeneic T-cell therapies to people with cancer.

Astellas and Adaptimmune will agree on up to three targets and co-develop T-cell therapy candidates directed to those targets. These targets will exclude target specific T-cell products in pre-clinical or clinical trials or those developed for other partners at Adaptimmune. The collaboration will leverage Adaptimmune's target identification and validation capabilities for generating target-specific T-cell Receptors (TCRs), chimeric antigen receptors (CARs), and HLA-independent TCRs that recognize surface epitopes independently of the HLA profile of the tumor cell. The collaboration will also utilize Astellas' Universal Donor Cell and Gene Editing Platform it obtained through the acquisition of Seattle-based Universal Cells.

Adaptimmune has been collaborating with Universal Cells (now an Astellas Company) since 2015 on development of gene-edited iPSC cell lines, for which Adaptimmune has rights to develop and commercialize resulting T-cell therapy products using its proprietary process for generating T-cells from stem cells without the use of feeder cell lines.

Astellas will fund research up until completion of a Phase 1 trial for each candidate. Upon completion of the Phase 1 trial for each candidate, Astellas and Adaptimmune will elect whether to progress with co-development and co-commercialization of the candidate, or to allow the other Party to pursue the candidate independently through a milestone and royalty bearing licence, with the agreement allowing for either company to opt out. The companies

will each have a co-exclusive licence covering the co-development and co-commercialization of the product candidates within the field of T-cell therapy. If a candidate is developed by one company only, the appropriate licences will become exclusive to the continuing party.

"Astellas positions immuno-oncology as one of its strategic areas of primary focus, and it is engaged in the development of novel therapies for cancer patients using a new modality/technology," stated Naoki Okamura, Representative Director Corporate Executive Vice President, Chief Strategy Officer and Chief Financial Officer, Astellas. "In addition to NK cells, T-cells are an important component of cell therapy for immuno-oncology, and we look forward that this agreement with Adaptimmune will enable us to create new stem-cell derived allogeneic T-cell therapies for a variety of cancers, including solid tumors, in the future. We will continue to dedicate our efforts in delivering novel treatments for diseases with high unmet medical needs, pursuing cutting-edge science and technological advances."

"We are delighted to establish this significant co-development partnership with Astellas, which builds upon and substantially extends an existing collaboration focused on gene editing of iPSC cells," said Helen Tayton-Martin, Adaptimmune's Chief Business Officer and Co-Founder. "This new collaboration may encompass both CAR-T and TCR T-cell approaches, including our novel HLA-independent TCR ("HiT") platform. It brings together highly complementary skills and expertise across the two organizations, and will enable the accelerated development of new, off-the-shelf T-cell therapy products for people with cancer."

Astellas will also have the right to select two targets and develop allogeneic cell therapy candidates independently. Astellas will have sole rights to develop and commercialize these products, subject to necessary licenses and the payment of milestones and royalties.

Under the terms of the agreement, Adaptimmune may receive up to \$897.5 million in payments, including:

- an upfront payment of \$50 million.
- development milestones totalling up to \$73.75 million for each product if the collaboration product discovered in this partnership is co-developed and commercialized by both companies
- Up to \$147.5 million in milestone payments per product and up to \$110 million in sales milestones for products developed unilaterally by Astellas.

In addition, Adaptimmune will receive research funding of up to \$7.5 million per year.

Finally, Adaptimmune would receive tiered royalties on net sales in the mid-single to mid-teen digits.

Under the terms of the agreement, Astellas may receive up to \$552.5 million, including:

- Up to \$147.5 million in milestone payments per product and up to \$110 million in sales milestones for products developed unilaterally by Adaptimmune.

In addition, Astellas would receive tiered royalties on net sales in the mid-single to mid-teen digits.

To the extent that Astellas and Adaptimmune co-develop and co-commercialize any T-cell therapy, they will equally share the costs of such co-development and co-commercialization, with the resulting profits from co-commercialization also shared equally. Further details governing co-development and co-commercialization will be articulated in a product-specific commercialization agreement.

The impact of this transaction on Astellas' financial results in the fiscal year ending March 31, 2020 will be limited.

### **About Adaptimmune**

Adaptimmune is a clinical-stage biopharmaceutical company focused on the development of novel cancer immunotherapy products for people with cancer. The Company's unique SPEAR (Specific Peptide Enhanced Affinity Receptor) T-cell platform enables the engineering of T-cells to target and destroy cancer across multiple solid tumors. For more information, please visit <http://www.adaptimmune.com>.

### **About Astellas**

Astellas Pharma Inc., based in Tokyo, Japan, is a company dedicated to improving the health of people around the world through the provision of innovative and reliable pharmaceutical products. For more information, please visit our website at <https://www.astellas.com/en>

### **Adaptimmune Forward-Looking Statements**

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). These forward-looking statements involve certain risks and uncertainties. Such risks and uncertainties could cause our actual results to differ materially from those indicated by such forward-looking statements, and include, without limitation: the success, cost and timing of our product development activities and clinical trials and our ability to successfully advance our TCR therapeutic candidates through the regulatory and commercialization processes. For a further description of the risks and uncertainties that could cause our actual results to differ materially from those expressed in these forward-looking statements, as well as risks relating to our business in general, we refer you to our Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (SEC) on November 6, 2019, and our other SEC filings. The forward-looking statements contained in this press release speak only as of the date the statements were made and we do not undertake any obligation to update such forward-looking statements to reflect subsequent events or circumstances.

### **Cautionary Notes Regarding Forward-Looking Statements (Astellas)**

In this press release, statements made with respect to current plans, estimates, strategies and beliefs and other statements that are not historical facts are forward-looking statements about the future performance of Astellas. These statements are based on management's current assumptions and beliefs in light of the information currently available to it and involve known and unknown risks and uncertainties. A number of factors could cause actual results to differ materially from those discussed in the forward-looking statements. Such factors include, but are not limited to: (i) changes in general economic conditions and in laws and regulations, relating to pharmaceutical markets, (ii) currency exchange rate fluctuations, (iii) delays in new product launches, (iv) the inability of Astellas to market existing and new products effectively, (v) the inability of Astellas to continue to effectively research and develop products accepted by customers in highly competitive markets, and (vi)

infringements of Astellas' intellectual property rights by third parties.

Information about pharmaceutical products (including products currently in development) which is included in this press release is not intended to constitute an advertisement or medical advice.

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