



Ascendis Pharma A/S Presents New Non-Clinical Data for TransCon™ TLR7/8 Agonist Oncology Program at SITC 2021

November 9, 2021

- In non-clinical models, a single dose of TransCon™ TLR7/8 Agonist activated critical innate and adaptive immune mechanisms, providing sustained modulation of tumor microenvironments with low systemic exposure.

- Company on track to announce initial monotherapy clinical data for TransCon TLR7/8 Agonist later this quarter.

COPENHAGEN, Denmark, Nov. 09, 2021 (GLOBE NEWSWIRE) -- Ascendis Pharma A/S (Nasdaq: ASND) today announced two poster presentations featuring new non-clinical data for its investigational TransCon™ TLR7/8 Agonist product candidate at SITC 2021, the annual meeting for the Society for Immunotherapy of Cancer taking place virtually and in person November 10-14 in Washington, D.C.

The data show that, as designed, TransCon TLR7/8 Agonist, which leverages the Company's innovative TransCon hydrogel technology, provides sustained activation of both innate and adaptive immune mechanisms with low systemic cytokine levels.

The posters being presented at SITC 2021 are:

Poster #769 Friday, November 12	A Single Dose of Intratumoral TransCon TLR7/8 Agonist Monotherapy Promoted Sustained Activation of Antigen Presenting Cells Resulting in CD4⁺ and CD8⁺ T Cell Activation and Tumor Growth Inhibition
Poster #16 Saturday, November 13	Tumor Growth Inhibition Mediated by a Single Dose of Intratumoral TransCon TLR7/8 Agonist Associated with Activated Circulating T and B cells and Sustained Low Levels of Systemic Cytokines

"We are designing TransCon TLR7/8 Agonist for sustained and controlled release of resiquimod, a potent TLR7/8 agonist, with the goal of maximizing therapeutic benefit and addressing the known limitations of current approaches, including serious systemic toxicity and rapid effusion from the tumor," said Juha Punnonen, Ascendis Pharma's Senior Vice President and Head of Oncology. "We are incredibly pleased to confirm with these non-clinical studies that a single intratumoral injection of sustained release unmodified resiquimod delivered through our unique hydrogel technology worked in the expected way. We look forward to sharing initial data from our Phase 1/2 clinical trial soon."

About TransCon TLR7/8 Agonist

TransCon TLR7/8 Agonist is an investigational long-acting prodrug of resiquimod, a small molecule agonist of Toll-like receptors (TLR) 7 and 8 designed to provide sustained activation of intratumoral antigen-presenting cells driving tumor antigen presentation and induction of immune stimulatory cytokines for weeks or months with a single intratumoral injection.

Ascendis Pharma is currently conducting a Phase 1/2 study, called the transcendIT-101 Study ([ClinicalTrials.gov](https://clinicaltrials.gov/ct2/show/study/NCT04799054) Identifier: NCT04799054), to evaluate TransCon TLR7/8 Agonist as monotherapy or in combination with pembrolizumab in dose escalation and dose expansion cohorts. The primary objectives are to evaluate safety and tolerability and to define the Maximum Tolerated Dose (MTD) and Recommended Phase 2 Dose (RP2D) of TransCon TLR7/8 Agonist alone or in combination with pembrolizumab.

About Ascendis Pharma A/S

Ascendis Pharma is applying its innovative platform technology to build a leading, fully integrated biopharma company focused on making a meaningful difference in patients' lives. Guided by its core values of patients, science and passion, the company uses its TransCon technologies to create new and potentially best-in-class therapies. Ascendis is headquartered in Copenhagen, Denmark, and has additional facilities in Heidelberg and Berlin, Germany; Palo Alto and Redwood City, California; and Princeton, New Jersey. Please visit www.ascendispharma.com to learn more.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding Ascendis' future operations, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to (i) Ascendis' plans to announce initial monotherapy clinical data for TransCon TLR7/8 Agonist, (ii) Ascendis' ability to apply its platform technology to build a leading, fully integrated biopharma company, and (iii) Ascendis' use of its TransCon technologies to create new and potentially best-in-class therapies. Ascendis may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Ascendis makes, including the following: dependence on third party manufacturers and distributors to supply TransCon hGH, the SKYTROFA® Auto-Injector and other study drug for commercial sales in the U.S. and clinical studies; unforeseen safety or efficacy results in its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs; unforeseen expenses related to commercialization of lonapegsomatropin-tcgd in the U.S., the co-pay program, and the further development of TransCon hGH, expenses related to the development and potential commercialization of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs, selling, general and administrative expenses, other research and development expenses and Ascendis' business generally; delays in the

development of its oncology programs, TransCon hGH, TransCon PTH and TransCon CNP or other development programs related to manufacturing, regulatory requirements, speed of patient recruitment or other unforeseen delays; dependence on third party manufacturers to supply study drug for planned clinical studies; Ascendis' ability to obtain additional funding, if needed, to support its business activities and the effects on its business from the worldwide COVID-19 pandemic. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to Ascendis' business in general, see Ascendis' Annual Report on Form 20-F filed with the U.S. Securities and Exchange Commission (SEC) on March 10, 2021 and Ascendis' other future reports filed with, or submitted to, the SEC. Forward-looking statements do not reflect the potential impact of any future licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments that Ascendis may enter into or make. Ascendis does not assume any obligation to update any forward-looking statements, except as required by law.

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