



Applied Therapeutics Announces Partnership with Advanz Pharma for Commercialization of AT-007 (Govorestat) in Europe

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- *Advanz Pharma will leverage its specialty, hospital, and rare disease expertise and infrastructure to commercialize AT-007 in Europe for both Galactosemia and SORD Deficiency*
- *Applied Therapeutics will receive milestone payments of over € 130 million and 20% royalty payments on net sales in Europe*
- Deal strengthens Applied Therapeutics' capital position and extends cash runway through key milestones

NEW YORK, Jan. 04, 2023 (GLOBE NEWSWIRE) -- Applied Therapeutics, Inc. (Nasdaq: APLT), a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates against validated molecular targets in indications of high unmet medical need, today announced a partnership with Advanz Pharma, a pharmaceutical company with a strategic focus on commercialization of specialty, hospital, and rare disease medicines, for commercialization of AT-007 (govorestat) in Europe.

"We believe Advanz Pharma is an ideal partner for commercialization of AT-007 in Europe," said Shoshana Shendelman, PhD, Founder and CEO of Applied Therapeutics. "Advanz Pharma's commitment to improving the lives of patients alongside their critical infrastructure and expertise in rare diseases positions them well for commercial success. This partnership brings us one step closer to making AT-007 available to patients with Galactosemia and SORD Deficiency – both debilitating rare diseases with no other therapies currently available – and strengthens Applied Therapeutics' capital position."

"We are pleased to partner with Applied Therapeutics," said Susanna El-Armale, Chief Corporate Development Officer of Advanz. "We believe that AT-007 represents a compelling scientific opportunity to treat rare diseases, including Galactosemia and SORD Deficiency. This partnership delivers on our commitment to bring innovative products to market that serve an unmet medical need and to build a strong product pipeline to drive Advanz's mid- and long-term growth."

Under the terms of the agreement:

- Applied Therapeutics will receive certain near-term development milestones upon clinical trial completion and marketing authorization in Europe as well as commercial sales milestones, which in the aggregate amount to over €130 million, including €10 million upfront due upon signing.
- Applied Therapeutics will receive royalties on any future net sales of AT-007 in Europe of 20%.
- Applied Therapeutics will continue to be responsible for the development, manufacturing and supply of AT-007, and Advanz Pharma will be responsible for packaging, distribution and commercialization in Europe.
- Advanz Pharma receives exclusive commercial rights in the European Economic Area, Switzerland, and the UK for AT-007 in Galactosemia and SORD Deficiency, with certain rights to future indications for AT-007 in Europe.

About AT-007

AT-007 is a central nervous system (CNS) penetrant Aldose Reductase inhibitor (ARI) in development for the treatment of several rare neurological diseases, including Galactosemia, SORD Deficiency, and PMM2-CDG. In clinical trials, AT-007 significantly reduced plasma galactitol levels vs. placebo in adults and children with Galactosemia. AT-007 is currently being studied in a Phase 3 clinical outcomes trial (ACTION-Galactosemia Kids) in children ages 2-17 with Galactosemia, as well as a long-term open-label study in adults with Galactosemia. In a pilot study in adults with SORD Deficiency, AT-007 significantly reduced blood sorbitol levels. AT-007 is currently being studied in a Phase 3 trial (INSPIRE) investigating biomarker efficacy and clinical outcomes in adults and children 16 years and older with SORD Deficiency. The drug has been generally safe and well tolerated in all clinical studies to date.

About Applied Therapeutics

Applied Therapeutics is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates against validated molecular targets in indications of high unmet medical need. The Company's lead drug candidate, AT-007, is a novel central nervous system penetrant Aldose Reductase Inhibitor (ARI) for the treatment of CNS rare metabolic diseases, including Galactosemia, SORD Deficiency, and PMM2-CDG. The Company is also developing AT-001, a novel potent ARI, for the treatment of Diabetic Cardiomyopathy, or DbCM, a fatal fibrosis of the heart. The preclinical pipeline also includes AT-003, an ARI designed to cross through the back of the eye when dosed orally, for the treatment of Diabetic retinopathy.

To learn more, please visit www.appliedtherapeutics.com and follow the company on Twitter @Applied_Tx.

About Advanz Pharma

ADVANZ PHARMA is a global pharmaceutical company with a strategic focus on specialty, hospital, and rare disease medicines in Europe and Canada. The company has commercial affiliates in Europe, North America and Australia, and a Centre of Excellence in Mumbai, India, as well as an

established global network of commercial partners throughout the rest of the world. With an agile and experienced team, including direct sales, marketing, and medical capabilities across Europe's major markets, Canada, and Australia, ADVANZ PHARMA is committed to improving lives of patients by providing and enhancing the specialty, hospital, and rare disease medicines they depend on. The company has a broad expertise in several therapeutic areas including hepatology, gastroenterology, CNS, critical care, anti-infectives, endocrinology, oncology, and more broadly rare disease medicines, making ADVANZ PHARMA a partner of choice for the commercialization of specialty, hospital, and rare disease medicines.

Forward-Looking Statements

This press release contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. Any statements, other than statements of historical fact, included in this press release regarding the strategy, future operations, prospects, plans and objectives of management, including words such as “may,” “will,” “expect,” “anticipate,” “plan,” “intend,” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are forward-looking statements. These include, without limitation, statements regarding (i) the anticipated benefits of the Company's partnership with Advanz Pharma and (ii) the expected development milestone payments. Forward-looking statements in this release involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by the forward-looking statements, and we, therefore cannot assure you that our plans, intentions, expectations or strategies will be attained or achieved.

Such risks and uncertainties include, without limitation, (i) our plans to develop, market and commercialize our product candidates, (ii) the initiation, timing, progress and results of our current and future preclinical studies and clinical trials and our research and development programs, (iii) our ability to take advantage of expedited regulatory pathways for any of our product candidates, (iv) our estimates regarding expenses, future revenue, capital requirements and needs for additional financing, (v) our ability to successfully acquire or license additional product candidates on reasonable terms and advance product candidates into, and successfully complete, clinical studies, (vi) our ability to maintain and establish collaborations or obtain additional funding, (vii) our ability to obtain and timing of regulatory approval of our current and future product candidates, (viii) the anticipated indications for our product candidates, if approved, (ix) our expectations regarding the potential market size and the rate and degree of market acceptance of such product candidates, (x) our ability to fund our working capital requirements and expectations regarding the sufficiency of our capital resources, (xi) the implementation of our business model and strategic plans for our business and product candidates, (xii) our intellectual property position and the duration of our patent rights, (xiii) developments or disputes concerning our intellectual property or other proprietary rights, (xiv) our expectations regarding government and third-party payor coverage and reimbursement, (xv) our ability to compete in the markets we serve, (xvi) the impact of government laws and regulations and liabilities thereunder, (xvii) developments relating to our competitors and our industry, (xviii) the impact of the COVID-19 pandemic on the timing and progress of our ongoing clinical trials and our business in general and (xix) other factors that may impact our financial results. In light of the significant uncertainties in these forward-looking statements, you should not rely upon forward-looking statements as predictions of future events. Although we believe that we have a reasonable basis for each forward-looking statement contained in this press release, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. Factors that may cause actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in our filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” contained therein. Except as otherwise required by law, we disclaim any intention or obligation to update or revise any forward-looking statements, which speak only as of the date they were made, whether as a result of new information, future events or circumstances or otherwise.

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