



Arena Pharmaceuticals and United Therapeutics Announce Global License Agreement for Ralinepag

November 15, 2018

- Arena will receive \$800M upfront, and is eligible to receive low double-digit tiered royalties, plus up to \$400M in milestone payments
- United Therapeutics will receive exclusive, worldwide rights to ralinepag - a potential best-in-class agent for the treatment of pulmonary arterial hypertension
- Arena to host conference call and webcast today at 8:30 AM EST

SAN DIEGO and RESEARCH TRIANGLE PARK, N.C., Nov. 15, 2018 /PRNewswire/ -- [Arena Pharmaceuticals, Inc.](#) (Nasdaq: ARNA) and [United Therapeutics Corporation](#) (Nasdaq: UTHR) today announced that the companies have entered into a global license agreement for Arena's Phase 3 investigational drug candidate, ralinepag, a next-generation, oral, selective and potent prostacyclin receptor agonist in development for the treatment of pulmonary arterial hypertension (PAH).



Under the terms of the agreement, Arena will grant United Therapeutics exclusive, worldwide rights to develop, manufacture and commercialize ralinepag. In return, Arena will receive up to \$1.2 billion, including an upfront payment of \$800 million and potential milestone payments totaling up to \$400 million based on the achievement of certain regulatory events. Additionally, Arena will receive low double-digit tiered royalties on annual net sales of ralinepag.

"We believe ralinepag has the potential to transform the treatment of PAH," said Amit D. Munshi, President and Chief Executive Officer of Arena. "We are thrilled to partner with United Therapeutics, based on their long-standing, deep commitment to the PAH community. This transaction represents a significant milestone in the development of ralinepag and will strategically position Arena to aggressively advance our best-in-class pipeline, anchored by etrasimod and olorinab, with the focus and resources essential for long-term success."

"We are very impressed with the clinical development plan and FDA coordination being managed by Arena," said Martine Rothblatt, Ph.D., Chairman and Chief Executive Officer of United Therapeutics. "We have conducted extensive due diligence on ralinepag, applying our two decades of knowledge about PAH. We are confident that after achieving FDA approval via at least one of its several different potential regulatory pathways to success, this product will help greater than 10,000 patients annually from the 2020s and well into the 2030s, while complementing our existing portfolio of PAH therapies."

The effectiveness of the agreement is conditioned on expiration or termination of the required waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.

Arena Conference Call and Webcast

Arena will host a conference call and live webcast open to the public today, November 15, 2018, at 8:30 AM EST / 5:30 AM PST.

When: November 15, 2018, 8:30 AM EST / 5:30 AM PST
Dial-in: (877) 643-7155 (United States) or (914) 495-8552 (International)
Conference ID: 4484624

Please join the conference call at least 10 minutes early to register. You can access the live webcast under the investor relations section of Arena's website at: www.arenapharm.com. A replay of the conference call will be archived under the [investor relations](#) section of Arena's website for 30 days shortly after the call.

About Ralinepag

Ralinepag (APD811) is a next-generation, oral, selective potent, once-daily IP receptor agonist intended for the treatment of pulmonary arterial hypertension (PAH). Arena discovered and developed this drug candidate internally. Ralinepag's potency on vasodilation, inhibition of proliferation of vascular smooth muscle cells, and inhibition of platelet aggregation, combined with an extended half-life, support its application as a potentially best-in-class agent for the treatment of PAH.

Ralinepag is an investigational compound that is not approved for any use in any country.

About Arena Pharmaceuticals

[Arena Pharmaceuticals](#) is driven to deliver novel, transformational medicines with optimized pharmacology and pharmacokinetics to patients globally. Arena's proprietary pipeline includes multiple potentially first- or best-in-class assets with broad clinical utility. [Etrasimod](#) (APD334), with potential utility in a broad range of immune and inflammatory conditions, is being evaluated in later-stage clinical programs in ulcerative colitis (UC) and Crohn's

disease, as well as progressing programs for primary biliary cholangitis (PBC) and atopic dermatitis. [Ralinepag](#) (APD811) is being evaluated in a Phase 3 program for pulmonary arterial hypertension (PAH). Arena is also evaluating [olorinab](#) (APD371) in a Phase 2 program for gastrointestinal pain. Arena continues to assess other earlier research and development stage drug candidates, including APD418 for decompensated heart failure.

In addition, Arena has several partnerships including with Everest Medicines Limited (ralinepag and etrasimod in Greater China and select Asian countries), Axovant Sciences GmbH (nelotanserin - Phase 2), Boehringer Ingelheim International GmbH (undisclosed target - preclinical), Outpost Medicine, LLC (undisclosed target – preclinical), and Eisai Co., Ltd. and Eisai Inc. (BELVIQ® - marketed product).

About United Therapeutics

[United Therapeutics Corporation](#) focuses on the strength of a balanced, value-creating biotechnology model. We are confident in our future thanks to our fundamental attributes, namely our obsession with quality and innovation, the power of our brands, our entrepreneurial culture and our bioinformatics leadership. We also believe that our determination to be responsible citizens – having a positive impact on patients, the environment and society – will sustain our success in the long term.

Through our wholly-owned subsidiary, Lung Biotechnology PBC, we are focused on addressing the acute national shortage of transplantable lungs and other organs with a variety of technologies that either delay the need for such organs or expand the supply. Lung Biotechnology is the first public benefit corporation subsidiary of a public biotechnology or pharmaceutical company. [uthr-g]

Forward-Looking Statements

Certain statements in this press release are forward-looking statements that involve a number of risks and uncertainties. These forward-looking statements may be identified by introductory words such as "will," "eligible," "potential," "in development for," "we believe," "we are confident," "conditioned on," "can," "intended for," "potentially," "driven to," "being evaluated for," "evaluating," "focuses on," "are focused on," "estimate," "anticipate," "project," "forecast," "intend," or words of similar meaning, or by the fact that they do not relate strictly to historical or current facts. Such forward-looking statements include, without limitation, statements about the license agreement between Arena and United Therapeutics, including its effectiveness, focus and potential payments to Arena; United Therapeutics' expertise and goals; the potential development, FDA approval and commercialization of ralinepag; the potential of ralinepag, including to be a best-in-class agent, to transform the treatment of PAH and to help greater than 10,000 patients annually from the 2020s and well into the 2030s; Arena's drive; the potential of Arena's assets, programs and collaborations; and United Therapeutics' focus, future and sustained long-term success. For such statements, Arena and United Therapeutics claim the protection of the Private Securities Litigation Reform Act of 1995. Actual events or results may differ materially from Arena's and United Therapeutics' expectations. Factors that could cause actual results to differ materially from the forward-looking statements include, without limitation, the following: the license agreement is subject to closing conditions, including regulatory approval, which may not be satisfied or occur; under the license agreement, United Therapeutics is not obligated to Arena to use any particular efforts to develop or commercialize ralinepag; results of clinical trials and other studies are subject to different interpretations and may not be predictive of future results; nonclinical and clinical data are voluminous and detailed, and regulatory agencies may interpret or weigh the importance of data differently and reach different conclusions than Arena, United Therapeutics or others, request additional information, have additional recommendations or change their guidance or requirements before or after approval; the timing and outcome of research, development and regulatory review is uncertain; the ability to obtain debt or other additional financing on favorable terms; Arena's expectations regarding the need to raise additional funds to advance all of its programs; you and others may not agree with the manner Arena and United Therapeutics allocate their resources; drug candidates may not advance in development or be approved for marketing; clinical trials and other studies may not proceed at the time or in the manner expected or at all; enrolling patients in ongoing and intended clinical trials is competitive and challenging; unexpected or unfavorable new data; risks related to developing and commercializing drugs, including regulatory, manufacturing and supply issues and the availability and use of ralinepag; risks and uncertainties relating to cash and revenues that may be generated from product sales or other sources, including the impact of competition; risks related to relying on partner performance; risks related to government and other third party actions, including decisions and other actions relating to approval, reimbursement and pricing; our and third parties' intellectual property rights; and satisfactory resolution of litigation or other disagreements with others. Additional factors that could cause actual results to differ materially from those stated or implied by forward-looking statements are disclosed in Arena's and United Therapeutics' filings with the Securities and Exchange Commission (SEC), including but not limited to our most recent Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q. We are providing this information as of November 15, 2018, and Arena and United Therapeutics disclaim any intent or obligation to update these forward-looking statements, other than as may be required under applicable law.

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