Revance and Mylan to Advance Development Program for Biosimilar to BOTOX®

June 1, 2020

- First neurotoxin formulation to be developed as a potential biosimilar product to BOTOX®, potentially giving Mylan access to 14 indications upon approval -

- $30 million milestone payable to Revance from Mylan -

NEWARK, Calif. & HERTFORDSHIRE, England & PITTSBURGH--(BUSINESS WIRE)--Jun. 1, 2020-- Revance Therapeutics, Inc. (NASDAQ: RVNC) and Mylan N.V. (NASDAQ: MYL) today announced Mylan's decision to move forward with a development plan, under a 351(k) pathway, for a proposed biosimilar to BOTOX® and BOTOX® Cosmetic (onabotulinumtoxinA), the market-leading neuromodulator.

Feedback obtained from the U.S. Food and Drug Administration (FDA) during a Biosimilar Initial Advisory Meeting (BIAM) held in February 2019 indicated that the 351(k) regulatory pathway for an onabotulinumtoxinA product is viable. Based on this meeting, along with the results from additional characterization and analysis completed by Revance, the two companies are now moving forward with the development program.

"We are excited to move forward with Revance on a clear and achievable development pathway for what will potentially be the first biosimilar to BOTOX®, and to leverage our worldwide reach and commercial expertise to maximize this exciting opportunity globally while expanding access to this important product for patients," said Mylan President Rajiv Malik. "This collaboration adds another high-profile, large-market, complex biologic, across both aesthetic and therapeutic categories, to our industry-leading biosimilars pipeline."

Added Mark Foley, President and Chief Executive Officer of Revance Therapeutics, "We are pleased with Mylan's decision to opt-in to the biosimilar to BOTOX development program, as it reflects our mutual confidence in the path forward. Assuming regulatory approval, it would allow us to financially participate in the short-acting neuromodulator market, while focusing our commercial efforts on creating the new, long-acting neuromodulator category."

Mylan and Revance signed a collaboration and license agreement in February 2018 for the development and regulatory approval of a biosimilar to BOTOX®, to be followed with commercialization by Mylan in the U.S., Europe and applicable markets throughout the rest of the world. The agreement included an upfront payment of $25 million to Revance. In August 2019, the companies amended the agreement to include an additional one-time payment of $5 million to extend the period in which Mylan could choose to continue its collaboration and license agreement to develop Revance's biosimilar to BOTOX®.

With Mylan's decision to move forward with the development program announced today, a payment of $30 million is now payable to Revance by Mylan. Furthermore, the collaboration and license agreement also provides for an additional $70 million in milestone payments, contingent upon the achievement of further clinical and regulatory milestones. Additionally, per the agreement, Revance is eligible to receive sales target milestone payments and royalties in all relevant markets.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which more than 40% of people being treated for HIV/AIDS globally depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our approximately 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com. We routinely post information that may be important to investors on our website at investor.mylan.com.

Forward-Looking Statement: Mylan

This press release includes statements that constitute "forward-looking statements," including with regard to the timing of regulatory approvals and commercialization of products; the outcome of clinical trials; the first neurotoxin formulation to be developed as a potential biosimilar product to BOTOX® potentially giving Mylan access to 14 indications upon approval; a decision to move forward with a development plan, under a 351(k) pathway, for a proposed biosimilar to BOTOX® and BOTOX® Cosmetic (onabotulinumtoxinA); that Mylan is excited to move forward with Revance on a clear and achievable development pathway, for what will potentially be the first biosimilar to BOTOX®, and to leverage our worldwide reach and commercial expertise to maximize this exciting opportunity globally while expanding access to this important product for patients; and potential future milestone and royalty payments. Because forward-looking statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such statements. Factors that could cause or contribute to such differences include, but are not limited to the potential widespread and highly uncertain impact of public health outbreaks, epidemics and pandemics, such as the COVID-19 pandemic; any changes in, interruptions to, or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings and the impact of any such proceedings on Mylan's or its partners' business; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

About Revance Therapeutics, Inc.

Revance Therapeutics, Inc. is a biotechnology company focused on innovative aesthetic and therapeutic offerings, including its next-generation neuromodulator product, DaxibotulinumtoxinA for Injection. DaxibotulinumtoxinA for Injection combines a proprietary stabilizing peptide excipient with a highly purified botulinum toxin that does not contain human or animal-based components. Revance has successfully completed a Phase 3 program for DaxibotulinumtoxinA for Injection in glabellar (frown) lines and is pursuing U.S. regulatory approval in 2020. Revance is also evaluating DaxibotulinumtoxinA for Injection in the full upper face, including glabellar lines, forehead lines and crow's feet, as well as in three therapeutic indications - cervical dystonia, adult upper limb spasticity and plantar fasciitis. Beyond DaxibotulinumtoxinA for Injection, Revance gained exclusive rights to commercialize TEOXANE SA's Resilient Hyaluronic Acid® (RHA®) line of fillers in the U.S., the first and only range of FDA-approved dermal fillers for correction of dynamic facial wrinkles and folds. Revance has also begun development of a biosimilar to BOTOX®, which would compete in the existing short-acting neuromodulator marketplace. Revance is dedicated to making a difference by transforming patient experiences. For more information or to join our team visit us at www.revance.com.

Forward-Looking Statement: Revance Therapeutics

This press release contains forward-looking statements, including statements related to Revance Therapeutics' 2020 financial outlook, expected cash runway and other financial performance, the process and timing of, and ability to complete, current and anticipated future clinical development of our investigational drug product candidates, the initiation, design, timing and results of our clinical studies, including the SAKURA 3 study of DaxibotulinumtoxinA for Injection, Phase 3 program for treatment of cervical dystonia, Phase 2 and other clinical programs for the management of plantar fasciitis and for the treatment of adult upper limb spasticity, and related results and reporting of such results; development of a biosimilar to BOTOX®; results of our non-clinical programs; statements about our business strategy, timeline and other goals and market for our anticipated products, plans and prospects; including our pre-commercialization plans and timing of our potential submission of a BLA filing for DaxibotulinumtoxinA for Injection to treat glabellar (frown) lines and potential regulatory approach and product launch; statements about our ability to obtain, and the timing relating to, regulatory approval with respect to our drug product candidates; statements regarding additional milestone payments through our partnerships, and potential benefits of our drug product candidates and our excipient peptide and other technologies. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from our expectations. These risks and uncertainties include, but are not limited to: the outcome, cost, and timing of our product development activities and clinical trials; the uncertain clinical development process, including the risk that clinical trials may not have an effective design or generate positive results; our ability to obtain and maintain regulatory approval of our drug product candidates; our ability to obtain funding for our operations; our plans to research, develop, and commercialize our drug product candidates; our ability to achieve market acceptance of our drug product candidates; unanticipated costs or delays in research, development, and commercialization efforts; the applicability of clinical study results to actual outcomes; the size and growth potential of the markets for our drug product candidates; our ability to successfully commercialize our drug product candidates and the timing of commercialization activities; the rate and degree of market acceptance of our drug product candidates; our ability to develop sales and marketing capabilities; the accuracy of our estimates regarding expenses, future revenues, capital requirements and needs for financing; our ability to continue obtaining and maintaining intellectual property protection for our drug product candidates; and other risks. Detailed information regarding factors that may cause actual results to differ materially from the results expressed or implied by statements in this press release may be found in Revance's periodic filings with the Securities and Exchange Commission (the "SEC"), including factors described in the section entitled "Risk Factors" of our quarterly report on Form 10-Q filed May 8, 2020. These forward-looking statements speak only as of the date hereof. Revance disclaims any obligation to update these forward-looking statements.

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Revance Contacts

INVESTORS
Revance Therapeutics, Inc.:
Jeanie Herbert, 714-325-3584
jherbert@revance.com
or
Gilmartin Group, LLC.:
Laurence Watts, 619-916-7620
laurence@gilmartinir.com

MEDIA
Revance Therapeutics, Inc.:
Sara Fahy, 949-887-4476
sfahy@revance.com
or
General Media:
Y&R:
Jenifer Slaw, 347-971-0906
jenifer.slaw@YR.com
or
Trade Media:
Nadine Tosk, 504-453-8344
nadinepr@gmail.com

Mylan Contacts

INVESTOR RELATIONS
Melissa Trombetta
724-514-1814

MEDIA
Mylan, Christine Waller
724-514-1968

Source: Revance Therapeutics, Inc.