

News Release

Media contact:

Sarah Freeman
(215) 510-4758
sfreem21@its.jnj.com

Investor contacts:

Christopher DelOrefice
(732) 524-2955

Lesley Fishman
(732) 524-3922

European Medicines Agency Grants PRIME and Advanced Therapy Medicinal Product Designations to Janssen's RPGR Gene Therapy for X-Linked Retinitis Pigmentosa

Only RPGR gene therapy program to receive PRIME designation

Designations will accelerate the regulatory review timeline of this potential gene therapy for European patients living with X-linked retinitis pigmentosa

RARITAN, NJ, March 2, 2020 – The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the European Medicines Agency (EMA) has granted both PRIME (PRIority MEdicines) and Advanced Therapy Medicinal Product (ATMP) designations to the company's adeno-associated virus (AAV)-RPGR gene therapy product for the treatment of inherited retinal disease X-linked retinitis pigmentosa (XLRP). PRIME is awarded to increase interactions, optimize development plans and accelerate innovative treatments where there is unmet medical need. Similarly, ATMP status is granted to medicines that are based on genes, tissues or cells and can offer groundbreaking opportunities for the treatment of disease. The novel AAV-RPGR asset, which is being jointly developed with MeiraGTx Holdings plc, also received Fast Track designation from the U.S. Food and Drug Administration (FDA) and Orphan designations from the FDA and the EMA.

The PRIME designation is based on data from the ongoing Phase 1/2 clinical trial (NCT03252847). For more information, visit:

<https://clinicaltrials.gov/ct2/show/NCT03252847?term=rpgr&draw=2&rank=1>.

“The PRIME and ATMP designations for our gene therapy asset are important achievements for Janssen’s growing retinal portfolio and bring us one step closer to delivering a transformational therapy to European patients living with X-linked retinitis pigmentosa,” said James List, M.D., Ph.D., Global Therapeutic Area Head, Cardiovascular & Metabolism, Janssen Research & Development, LLC. “We look forward to partnering with the EMA and appreciate their dedication to patients underserved with current options.”

XLRP represents one of the most severe forms of retinitis pigmentosa, resulting in juvenile onset and progression to legal blindness in adulthood. Currently, there are no approved treatments. Janssen’s AAV-RPGR gene therapy is designed to treat the most common form of XLRP, caused by mutations in the RPGR gene, by slowing the retinal degeneration and preserving visual function.

In January 2019, Janssen entered into a worldwide collaboration and license agreement with MeiraGTx Holdings plc, a clinical stage gene therapy company, to develop, manufacture and commercialize its inherited retinal disease portfolio. AAV-RPGR gene therapy is being developed under this collaboration and license agreement. The companies also formed a research collaboration to explore new targets for other inherited retinal diseases and further develop AAV manufacturing technology.

About Janssen’s Retinal Portfolio

At Janssen, we are translating our understanding of the biology underlying retinal diseases to develop needed therapies that preserve and enhance vision. Janssen’s clinical-stage portfolio includes leading product candidates for inherited retinal diseases achromatopsia and X-linked retinitis pigmentosa. Janssen is also expanding into more common eye diseases using mRNA-targeted therapy to treat

conditions, including wet age-related macular degeneration, diabetic retinopathy and diabetic macular edema.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Disease & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at www.janssen.com. Follow us on Twitter @JanssenGlobal. Janssen Research & Development, LLC is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding the potential benefits of the collaboration and license agreement with MeiraGTx Holdings plc. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting

in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 29, 2019, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's subsequent Quarterly Reports on Form 10-Q, and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Neither the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

#