Bristol-Myers Squibb and uniQure Enter into Exclusive Strategic Collaboration to Develop Gene Therapies for Cardiovascular Diseases

Release Date:
Monday, April 6, 2015 7:32 am EDT

Terms:
R&D News  Partnering News

Dateline City:
NEW YORK & AMSTERDAM

NEW YORK & AMSTERDAM--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMY) and uniQure N.V. (NASDAQ:QURE) announced today an agreement that provides Bristol-Myers Squibb with exclusive access to uniQure's gene therapy technology platform for multiple targets in cardiovascular diseases. The collaboration includes uniQure’s proprietary gene therapy program for congestive heart failure that is intended to restore the heart’s ability to synthesize S100A1, a calcium sensor and master regulator of heart function, and thereby improve clinical outcomes for patients with reduced ejection fraction. Beyond cardiovascular diseases, the agreement also includes the potential for target-exclusive collaboration in other disease areas. In total, the companies may collaborate on ten targets, including S100A1.

uniQure will lead discovery efforts and be responsible for manufacturing of clinical and commercial supplies using its vector technologies and its industrial, proprietary insect-cell based manufacturing platform. Bristol-Myers Squibb will lead development and regulatory activities across all programs and be responsible for all research and development costs. Bristol-Myers Squibb will be solely responsible for commercialization of all products from the collaboration.

“Bristol-Myers Squibb has an excellent and long-standing track record of success in discovering and developing treatments for cardiovascular diseases and in embracing advancing technologies for the treatment of human diseases,” said Carl Decicco, Ph.D., Head of Discovery, R&D, Bristol-Myers Squibb. “Collaborating with uniQure, a clear leader in the field with an innovative and validated gene therapy platform, further strengthens our capability to bring forward transformational new therapeutics for difficult-to-treat diseases, including cardiovascular diseases such as heart failure.”

“Bristol-Myers Squibb’s strength in the cardiovascular area and its commitment to gene therapy will allow them to leverage the full breadth and capacity of our platform for cardiovascular diseases,” said Joern Aldag, Chief Executive Officer of uniQure. “This collaboration will accelerate the application of gene therapy for large patient populations suffering from heart diseases and will complement the further development of uniQure’s internal pipeline in two focus areas: liver diseases, including hemophilia, and CNS, including lysosomal storage diseases.”

Under the terms of the agreement, Bristol-Myers Squibb will make near-term payments of approximately $100 million, including an upfront payment of $50 million to be made at the closing of the transaction, a $15 million payment for the selection of three collaboration targets, in addition to S100A1, to be made within three months of the closing and an initial equity investment in uniQure for a number of shares that will equal 4.9% of the total number of shares outstanding following such issuance, at a purchase price of $33.84 per share, or at least $32 million in total. Bristol-Myers-Squibb will acquire an additional 5.0% ownership before December 31, 2015, at a 10% premium, and will be granted two warrants to acquire up to an additional 10% equity interest, at a premium, based on additional targets being introduced into the collaboration. The parties have also agreed to enter into a supply contract, under which uniQure will undertake manufacturing of all gene therapy products under the collaboration.

uniQure will be eligible to receive research, development and regulatory milestone payments, including up to $254 million for the lead S100A1 therapeutic and up to $217 million for each other gene therapy product potentially developed under the collaboration. uniQure is also eligible to receive net sales based milestone payments and tiered single to double-digit royalties on product sales.

“It is immensely exciting to see the potential of our initial discoveries recognized first by uniQure and then advanced to a stage where we can build a portfolio of gene therapies to treat cardiovascular disease in partnership with Bristol-Myers Squibb,” added Prof. Dr. Patrick Most, Managing Director of uniQure Germany (formerly known as InoCard). “I would like to thank my colleagues in Heidelberg, Amsterdam and Lexington, Massachusetts for the teamwork that has contributed to bringing the lead S100A1 therapeutic closer to helping patients.”

uniQure and Bristol-Myers Squibb anticipate the collaboration to be effective during the second quarter of 2015. The effectiveness of the transaction is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino Antitrust Improvements Act. The initial issuance by uniQure of equity to Bristol-Myers Squibb also is anticipated to close in the second quarter of 2015 and is subject to the approval by the shareholders of uniQure.

About Bristol-Myers Squibb
Bristol-Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop and deliver innovative medicines that help patients prevail over serious diseases. For more information, please visit www.bms.com or follow us on Twitter at http://twitter.com/bmsnews.
About uniQure

uniQure is delivering on the promise of gene therapy through single treatments with potentially curative results. We have developed a modular platform to rapidly bring new disease-modifying therapies to patients with severe disorders. We are engaged in multiple partnerships and have obtained regulatory approval of our lead product, Glybera, in the European Union for a subset of patients with LPLD. www.uniQure.com

Bristol-Myers Squibb Forward-Looking Statement

This press release contains “forward-looking statements” as that term is defined in the Private Securities Litigation Reform Act of 1995 regarding the research, development and commercialization of pharmaceutical products. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among other risks, there can be no guarantee that any of the investigational gene therapy programs described in this release will be successful. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Bristol-Myers Squibb’s business, particularly those identified in the cautionary factors discussion in Bristol-Myers Squibb’s Annual Report on Form 10-K for the year ended December 31, 2014 in our Quarterly Reports on Form 10-Q and our Current Reports on Form 8-K. Bristol-Myers Squibb undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise.

uniQure Forward-Looking Statement

This press release contains forward-looking statements. All statements other than statements of historical fact are forward-looking statements, which are often indicated by terms such as “anticipate,” “believe,” “could,” “estimate,” “expect,” “goal,” “intend,” “look forward to,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “will,” “would” and similar expressions. Forward-looking statements are based on management’s beliefs and assumptions and on information available to management only as of the date of this press release. These forward-looking statements include, but are not limited to, statements regarding the development of gene therapies for cardiovascular disease, the success of our collaboration with Bristol-Myers Squibb, the election by Bristol-Myers Squibb to extend the range of target indications covered by our collaboration, and the risk of cessation, delay or lack of success of any of our ongoing or planned clinical studies and/or development of our product candidates. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including, without limitation, risks associated with collaboration arrangements, our and our collaborators’ clinical development activities, regulatory oversight, product commercialization and intellectual property claims, as well as the risks, uncertainties and other factors described under the heading “Risk Factors” in uniQure’s 2013 Annual Report on Form 20-F filed with the Securities and Exchange Commission on April 25, 2014 and its 2014 Annual Report on Form 20-F to be filed with the Securities and Exchange Commission. Given these risks, uncertainties and other factors, you should not place undue reliance on these forward-looking statements, and we assume no obligation to update these forward-looking statements, even if new information becomes available in the future.

Language:
English

Contact:
Media:
Bristol-Myers Squibb
Sarah Koenig, 609-252-4145
sarah.koenig@bms.com
or
MacDougall Biomedical Communications
Gretchen Schweitzer
Direct: +49 172 861 8540
Main: +49 89 2424 3494 or +1 781 235 3060
gschweitzer@macbiocom.com
or
Investor Relations:
Bristol-Myers Squibb
Ranya Dajani, 609-252-5330
ranya.dajani@bms.com
or
uniQure
Aicha Diba
Direct: +31 20 240 6100
Main: +31 20 240 6000
a.diba@uniQure.com

Ticker Slug:
Ticker: BMY
Exchange: NYSE
Ticker: QURE
Exchange: NASDAQ
