



Genzyme Strengthens Endocrinology Portfolio with Acquisition of Rare Disease Therapy Caprelsa® (vandetanib) from AstraZeneca

Paris, France - July 27, 2015 - [Sanofi](#) and its subsidiary [Genzyme](#) announced today that it has entered into a definitive agreement with AstraZeneca to acquire Caprelsa® (vandetanib), a rare disease therapy, indicated for the treatment of symptomatic or progressive medullary thyroid carcinoma in patients with unresectable locally advanced or metastatic disease.

Caprelsa is an oral kinase inhibitor treatment and is currently available in 28 countries. Caprelsa is in Phase III development for differentiated thyroid carcinoma, with the study expected to finish in the second half of 2015.

“The addition of Caprelsa represents a strong strategic fit for our rare Endocrinology portfolio and underscores Genzyme’s commitment to addressing unmet needs in the thyroid community,” said David Meeker, M.D., Genzyme’s President and CEO. *“We look forward to bringing our rare disease expertise to appropriate patients with advanced stage thyroid carcinoma.”*

The acquisition builds on Genzyme’s long-standing commitment and scientific leadership in the field of endocrinology globally. Under the terms of the agreement, Genzyme will pay AstraZeneca up to \$300 million, including an upfront payment of \$165 million to acquire the global rights to sell and further develop Caprelsa, and further development and sales milestone payments of up to \$135 million. The transaction does not include the transfer of any AstraZeneca employees or facilities.

Luke Miels, Executive Vice President, Global Product & Portfolio Strategy and Corporate Affairs, AstraZeneca, said: *“Caprelsa is a rare disease therapy and the divestment to Genzyme, an expert leader in endocrinology, demonstrates our commitment to ensure patients continue to have access to this medicine while we sharpen our focus on key disease areas.”*

The transaction is subject to closing conditions, including the receipt of antitrust clearance from the US Federal Trade Commission. The transaction is expected to complete in the second half of 2015.

CAPRELSA (vandetanib) US Indication

CAPRELSA is indicated for the treatment of symptomatic or progressive medullary thyroid cancer in patients with unresectable locally advanced or metastatic disease.

Use CAPRELSA in patients with indolent, asymptomatic or slowly progressing disease only after careful consideration of the treatment related risks of CAPRELSA.

Important Safety Information, Including Boxed WARNING, for CAPRELSA

<p>WARNING: QT PROLONGATION, TORSADES DE POINTES, AND SUDDEN DEATH</p> <ul style="list-style-type: none">• CAPRELSA can prolong the QT interval. Torsades de pointes and sudden death have occurred in patients receiving CAPRELSA



- Do not use CAPRELSA in patients with hypocalcemia, hypokalemia, hypomagnesemia, or long QT syndrome. Correct hypocalcemia, hypokalemia and/or hypomagnesemia prior to CAPRELSA administration
- Monitor electrolytes periodically
- Avoid drugs known to prolong the QT interval
- Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA

- Do not use in patients with congenital long QT syndrome
- CAPRELSA can prolong the QT interval in a concentration-dependent manner. Torsades de pointes, ventricular tachycardia and sudden deaths have occurred in patients treated with CAPRELSA
- Do not start CAPRELSA treatment in patients whose QTcF interval (corrected QT interval, Fridericia) is greater than 450 ms or who have a history of Torsades de pointes, bradyarrhythmias, or uncompensated heart failure. CAPRELSA has not been studied in patients with ventricular arrhythmias or recent myocardial infarction
- Stop CAPRELSA in patients who develop a QTcF greater than 500 ms until QTcF returns to less than 450 ms. Dosing of CAPRELSA can then be resumed at a reduced dose
- Because of the risk of QT prolongation, obtain an ECG and serum potassium, calcium, magnesium, and thyroid-stimulating hormone (TSH) at baseline, 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter. Following any dose reduction or interruptions greater than 2 weeks, conduct QT assessments as described above
- Severe skin reactions (including Stevens-Johnson syndrome), some leading to death, have occurred in patients treated with CAPRELSA. Consider permanent discontinuation of CAPRELSA for severe skin reactions
- Photosensitivity reactions can occur during CAPRELSA treatment and up to 4 months after treatment discontinuation
- Interstitial lung disease (ILD) or pneumonitis, including fatalities, has occurred in patients treated with CAPRELSA. Interrupt CAPRELSA for acute or worsening pulmonary symptoms and discontinue CAPRELSA if ILD is confirmed
- Ischemic cerebrovascular events, including fatalities, occurred in patients treated with CAPRELSA. The safety of resumption of CAPRELSA therapy after resolution of an ischemic cerebrovascular event has not been studied. Discontinue CAPRELSA in patients who experience a severe ischemic cerebrovascular event
- Serious hemorrhagic events, including fatalities, occurred in patients treated with CAPRELSA. Do not administer CAPRELSA to patients with a recent history of hemoptysis of $\geq 1/2$ teaspoon of red blood. Discontinue CAPRELSA in patients with severe hemorrhage
- Heart failure, including fatalities, occurred in patients treated with CAPRELSA. Monitor for signs and symptoms of heart failure. Consider discontinuation of CAPRELSA in patients with heart failure. Heart failure may not be reversible upon stopping CAPRELSA
- Diarrhea of Grade 3 or greater severity occurred in patients receiving CAPRELSA. If diarrhea occurs, carefully monitor serum electrolytes and ECGs to enable early detection of QT prolongation resulting from dehydration. Interrupt CAPRELSA for severe diarrhea and upon improvement resume CAPRELSA at a reduced dose
- Increased dosing of thyroid replacement therapy was required in 49% of CAPRELSA-treated patients. Obtain TSH at baseline, at 2-4 weeks and 8-12 weeks after starting treatment with CAPRELSA, and every 3 months thereafter. If signs or symptoms of hypothyroidism occur, examine thyroid hormone levels and adjust thyroid replacement therapy accordingly



- Hypertension, including hypertensive crisis, has occurred in patients treated with CAPRELSA. Monitor all patients for hypertension. Dose reduction or interruption for hypertension may be necessary. If hypertension cannot be controlled, do not resume CAPRELSA
- Reversible posterior leukoencephalopathy syndrome (RPLS) has occurred in patients treated with CAPRELSA. Consider this syndrome in any patient presenting with seizures, headache, visual disturbances, confusion or altered mental function. In clinical studies, three of four patients who developed RPLS while taking CAPRELSA also had hypertension. Discontinue CAPRELSA treatment in patients with RPLS
- Avoid administration of CAPRELSA with anti-arrhythmic drugs and other drugs that may prolong the QT interval
- Vandetanib exposure is increased in patients with impaired renal function. Reduce the starting dose to 200 mg in patients with moderate to severe renal impairment and monitor the QT interval closely. There is no information available for patients with end-stage renal disease requiring dialysis
- CAPRELSA is not recommended for patients with moderate and severe hepatic impairment, as safety and efficacy have not been established
- CAPRELSA can cause fetal harm when administered to a pregnant woman. Women of childbearing potential should avoid pregnancy and be advised that they must use effective contraception during CAPRELSA treatment and for at least 4 months following the last dose of CAPRELSA
- The most commonly reported adverse drug reactions (>20%) seen with CAPRELSA and with a between arm difference of $\geq 5\%$ are diarrhea/colitis (57%), rash (53%), acneiform dermatitis (35%), hypertension (33%), nausea (33%), headache (26%), upper respiratory tract infections (23%), decreased appetite (21%), and abdominal pain (21%)
- **CAPRELSA REMS Program:** Because of the risks of QT prolongation, Torsades de pointes, and sudden death, CAPRELSA is available only through the CAPRELSA REMS Program. Only prescribers and pharmacies certified with the restricted distribution program are able to prescribe and dispense CAPRELSA. To learn about the specific REMS requirements and to enroll in the CAPRELSA REMS Program, call **1-800-236-9933** or visit www.caprelsarems.com

About Genzyme, a Sanofi Company

Genzyme has pioneered the development and delivery of transformative therapies for patients affected by rare and debilitating diseases for over 30 years. We accomplish our goals through world-class research and with the compassion and commitment of our employees. With a focus on rare diseases and multiple sclerosis, we are dedicated to making a positive impact on the lives of the patients and families we serve. That goal guides and inspires us every day. Genzyme's portfolio of transformative therapies, which are marketed in countries around the world, represents groundbreaking and life-saving advances in medicine. As a Sanofi company, Genzyme benefits from the reach and resources of one of the world's largest pharmaceutical companies, with a shared commitment to improving the lives of patients. Learn more at www.genzyme.com.

About Sanofi

Sanofi, a global healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and Genzyme. Sanofi is listed in Paris (EURONEXT: [SAN](http://www.sanofi.com)) and in New York (NYSE: [SNY](http://www.sanofi.com)).

About AstraZeneca

AstraZeneca is a global, innovation-driven biopharmaceutical business that focuses on the discovery, development and commercialisation of prescription medicines, primarily for the treatment of cardiovascular, metabolic, respiratory, inflammation, autoimmune, oncology, infection and neuroscience diseases. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: www.astrazeneca.com



Sanofi Forward-Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words “expects”, “anticipates”, “believes”, “intends”, “estimates”, “plans” and similar expressions. Although Sanofi’s management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group’s ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under “Risk Factors” and “Cautionary Statement Regarding Forward-Looking Statements” in Sanofi’s annual report on Form 20-F for the year ended December 31, 2014. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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