Pfizer Achieves Primary Endpoint With Phase 3B Top-Line Results Of GENOTROPIN® In Very Young Children Born Small For Gestational Age

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Pfizer Inc. (NYSE:PFE) announced today the top-line results from a Phase 3B study evaluating the 24-month efficacy of GENOTROPIN® (somatropin) on the height in small-for-gestational-age (SGA) children 24-30 months old. The primary endpoint of the study was achieved: there was a statistically significant difference at 24 months in change from baseline height between patients treated with GENOTROPIN and those in the untreated control group, as measured by height standard deviation score (SDS).

The study was intended to generate additional data regarding the safety and efficacy of GENOTROPIN treatment in subjects born SGA who fail to achieve catch-up growth by two years of age. The study results showed, after 24 months of treatment, the GENOTROPIN group had a statistically significantly greater gain in height SDS compared to the untreated control group.

The study was a controlled, multi-center study, randomizing SGA children to GENOTROPIN or an untreated control group. There were 43 participants from 16 centers in eight European countries, including Spain, Italy, Belgium, Switzerland, Czech Republic, Germany, Sweden and Netherlands. Participants in the study were between 24-30 months old and were randomized in a 1:1 ratio to receive GENOTROPIN 0.035 mg/kg/d or no treatment.

A total of 39 participants completed the study, with two GENOTROPIN participants and two control-group participants withdrawing from the study. A total of 14 serious adverse events were reported in eight participants. Two serious adverse events, occurring to one participant, were deemed to be related to treatment with GENOTROPIN. The adverse events observed in the study were consistent with the known safety profile of GENOTROPIN.

About GENOTROPIN

GENOTROPIN is a man-made, prescription treatment option, approved in the United States for children who do not make enough growth hormone on their own, have the genetic condition called Prader-Willi syndrome (PWS), were born smaller than most other babies, have the genetic condition called Turner syndrome (TS) or have idiopathic short stature (ISS). GENOTROPIN is also approved to treat adults with growth hormone deficiency. GENOTROPIN is taken by injection just below the skin and is available in a wide range of devices to fit a range of individual dosing needs. GENOTROPIN is just like the natural growth hormone that our bodies make and has an established safety profile.

Important GENOTROPIN® Safety Information

Growth hormone should not be used to increase height in children after the growth plates have closed. Growth hormone should not be used in patients with diabetes who have certain types of diabetic retinopathy (eye problems). Growth hormone should not be used in patients with cancer or who are being treated for cancer. Growth hormone deficiency can be caused by brain tumors. So, the presence of these brain tumors should be ruled out before treatment is started. Growth hormone should not be used if it is shown that a previous brain tumor has come back or is getting larger. Growth hormone should not be used in patients who are critically ill because of surgery, trauma, or respiratory failure. Growth hormone should not be used in children with Prader-Willi syndrome who are very overweight or have severe breathing problems. GENOTROPIN should not be used by patients who have had an allergy or bad reaction to somatropin or any of the other ingredients in GENOTROPIN. Some patients have developed diabetes mellitus while taking GENOTROPIN. Dosage of diabetes medicines may need to be adjusted during growth hormone treatment. Patients should be watched carefully if growth hormone is given along with glucocorticoid therapy and/or other drugs that are processed by the body in the same way. In childhood cancer survivors, treatment with growth hormone may increase the risk of a new tumor, particularly certain benign brain tumors. This risk may be higher in patients who were treated with cranial radiation. Also, patients and their doctors should check regularly for any skin changes. A small number of patients treated with growth hormone have had increased pressure in the brain. This can cause

headaches and problems with vision. Treatment should be stopped and reassessed in these patients. Patients with Turner syndrome and Prader-Willi syndrome may be at higher risk of developing increased pressure in the brain. Thyroid function should be checked regularly during growth hormone therapy. Thyroid hormone replacement therapy should be started or adjusted if needed. Patients treated with growth hormone should be checked regularly if they are receiving standard hormone replacement therapy to treat a lack of more than one hormone. In children experiencing rapid growth, curvature of the spine may develop or worsen. This is also called scoliosis. Patients with scoliosis should be checked regularly to make sure their scoliosis does not get worse during their growth hormone therapy. In children experiencing rapid growth, limping or hip or knee pain may occur. If a child getting growth hormone therapy starts to limp or gets hip or knee pain, the child’s doctor should be notified and the child should be examined. Growth hormone should only be used during pregnancy if clearly needed. It should be used with caution in nursing mothers because it is not known whether growth hormone is passed into human milk. Use a different place on the body each day for growth hormone injections. This can help to prevent skin problems such as lumpiness or soreness. Some cases of pancreatitis (inflamed pancreas) have been reported rarely in children and adults receiving growth hormone. There is some evidence that there is a greater risk of this in children than in adults. Literature suggests that girls who have Turner syndrome may have a greater risk of pancreatitis than other children taking growth hormone. In any child who develops lasting, severe abdominal pain, pancreatitis should be considered. In studies of GENOTROPIN in children with GHD, side effects included injection site reactions, such as pain, redness/swelling, inflammation, bleeding, scarring, lumps, or rash. Other side effects were fat loss, headache, blood in the urine, low thyroid activity, and mildly increased blood sugar. In studies of GENOTROPIN in children born SGA, side effects included temporarily elevated blood sugar, increased pressure in the brain, early puberty, abnormal jaw growth, injection site reactions, growth of moles, and worsening of scoliosis (curvature of the spine). Deaths have been reported with the use of growth hormone in children with Prader-Willi syndrome. These children were extremely overweight, had breathing problems, and/or lung infection. All patients with Prader-Willi syndrome should be examined for these problems. They should also establish healthy weight control. In studies of GENOTROPIN in children with PWS, side effects included fluid retention, aggressiveness, joint and muscle pain, hair loss, headache, and increased pressure in the brain. Turner syndrome patients taking growth hormone therapy may be more likely to get ear infections. This is also called otitis media. In studies of GENOTROPIN in children with Turner syndrome, side effects included flu, throat, ear, or sinus infection, runny nose, joint pain, and urinary tract infection. In studies of GENOTROPIN in children with ISS, side effects included respiratory illnesses,

flu, throat infection, inflammation of the nose and throat, stomach pain, headaches, increased appetite, fever, fracture, mood changes, and joint pain. Women who are taking estrogen by mouth may take GENOTROPIN. They may need a larger dose of growth hormone. GENOTROPIN may be taken by the elderly. Elderly patients may be more likely to have side effects with growth hormone therapy. In studies of GENOTROPIN in adults with GHD, side effects included fluid retention, joint or muscle pain, stiffness, and changes in sensation. Usually these side effects did not last long and depended on the dose of GENOTROPIN being taken. GENOTROPIN cartridges contain m-Cresol and should not be used by patients allergic to it. A health care provider will help you with the first injection. He or she will also train you on how to inject GENOTROPIN.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For the full Prescribing Information for GENOTROPIN, please visit http://labeling.pfizer.com/ShowLabeling.aspx?id=577.

GENOTROPIN Indications and Usage in the U.S.

GENOTROPIN is a prescription product for the treatment of growth failure in children:

Who do not make enough growth hormone on their own. This condition is called growth hormone deficiency (GHD). With a genetic condition called Prader-Willi syndrome (PWS). Growth hormone is not right for all children with PWS. Check with your doctor. Who were born smaller than most other babies born after the same number of weeks of pregnancy. Some of these babies may not show catch-up growth by age 2 years. This condition is called small for gestational age (SGA). With a genetic condition called Turner syndrome (TS). With idiopathic short stature (ISS), which means that they are shorter than 98.8% of other children of the same age and sex; they are growing at a rate that is not likely to allow them to reach normal adult height, and their growth plates have not closed. Other causes of short height should be ruled out. ISS has no known cause.
GENOTROPIN is a prescription product for the replacement of growth hormone in adults with growth hormone deficiency (GHD) that started either in childhood or as an adult. Your doctor should do tests to be sure you have GHD, as appropriate.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-

known consumer health care products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more, please visit us atwww.pfizer.com.

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