Phase III Trial of Novartis Drug AfinitorÃ,® Met Primary Endpoint of Reducing SEGA Tumor Size in Patients With Tuberous Sclerosis

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EAST HANOVER, N.J., July 8, 2011 /PRNewswire/ -- Novartis Pharmaceuticals Corporation ("Novartis") announced today Phase III trial results that showed more than one-third of patients taking Afinitor® (everolimus) tablets* experienced a 50% or greater reduction in the size of their subependymal giant cell astrocytomas (SEGAs), non-cancerous brain tumors associated with tuberous sclerosis complex (TSC)(1,2,6). This study, the largest prospective clinical trial to date in this patient population, is being presented on Saturday, July 9 at the International TSC Research Conference in Washington, D.C.

Currently, Afinitor is approved in the US for the following indication: to treat patients with SEGA associated with tuberous sclerosis who require therapeutic intervention but are not candidates for curative surgical intervention. The effectiveness of everolimus is based on an analysis of change in SEGA volume. Additionally, the indication states, clinical benefit such as improvement in disease-related symptoms or increase in overall survival has not been shown(7).

Tuberous sclerosis complex affects approximately 25,000 to 40,000 people in the US and one to two million people worldwide, and is associated with a variety of resulting disorders including seizures, swelling in the brain (hydrocephalus), developmental delays and skin lesions(2,6). Also known as tuberous sclerosis (TS), TSC is a genetic disorder that may cause non-cancerous tumors to form in vital organs and can affect many different parts of the body, most commonly the brain and kidney(6,8). Signs and symptoms of TSC vary depending on which system and which organs are involved(6). SEGAs occur in up to 20% of patients with TSC. In countries where everolimus is not approved, brain surgery is the only treatment option for patients with growing SEGAs(2).

The 117-patient, randomized, placebo-controlled Phase III EXIST-1 (EXamining everolimus In a Study of TSC) trial met its primary endpoin
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