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NEWS RELEASE

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Tuberous Sclerosis Alliance Announces FDA Approval of First Drug to Treat Tuberous Sclerosis Complex

Silver Spring, MD – The Tuberous Sclerosis Alliance (TS Alliance) today announced the first drug approved for a tuberous sclerosis complex (TSC) indication by the Federal Drug Administration (FDA). This drug, manufactured by Novartis Oncology, is called Afinitor and will be used to treat subependymal giant cell astrocytomas (SEGAs) in individuals with TSC. This type of tumor develops in approximately 15-20 percent of individuals with TSC, and typically becomes symptomatic in children and adolescents, and rarely in adults.

“SEGAs can be challenging for individuals with tuberous sclerosis complex and for the whole family, which is why we are encouraged to see ongoing research and new treatment options for these individuals,” said Vicky Whittemore, Ph.D., TS Alliance Vice President and Chief Scientific Officer. “Prior to Afinitor the only treatment option for individuals with growing SEGAs, many of them children, was brain surgery.”

“At the TS Alliance, it’s crucial for us to raise awareness about the tuberous sclerosis complex, as many individuals go undiagnosed or even misdiagnosed,” explained Kari Luther Rosbeck, President and Chief Executive Officer for the TS Alliance. “Therefore, it’s important that anyone with TSC get the care needed by having multiple treatment options available.”

“TSC research has moved from the identification of the genes for TSC in the 1990s to clinical trials in recent years, and the development of new treatment options for all of the symptoms of TSC is our priority,” Whittemore continued. “This is the first treatment that has been approved by the FDA specifically for TSC, and Afinitor offers a new treatment option for individuals with the disease.”

“Because identifying new treatments is so important, the TS Alliance instituted a new TSC Drug Screening Program in 2010, which will help drive and accelerate basic and translational research,” Rosbeck said. According to Rosbeck, the program provides funding to test drugs that are already FDA-approved or new compounds in animal models of TSC in order to fast-track the translation of basic research to new treatments for patients.

“By bringing together biotech and pharmaceutical companies with researchers interested in TSC, our hope is that we can accelerate the testing of new treatments for TSC,” added Dr. Whittemore.

The TS Alliance is the only national voluntary health organization dedicated to finding a cure for tuberous sclerosis complex (TSC) and improving the lives of those affected. TSC is a multi-system genetic disorder affecting many parts of the body, primarily due to the growth of tumors in the vital organs, such as the brain, heart, kidneys, lungs, eyes and skin. People with TSC commonly have epilepsy, behavioral disorders (such as attention deficit disorder-ADD), skin disorders (such as lesions) and other symptoms. TSC is estimated to affect nearly 50,000 people in the U.S., and more than 1 million worldwide.

For more information about the TS Alliance or TSC, call (800) 225-6872 or visit www.tsalliance.org.

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