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Rasilez® receives EU approval, the first major innovation in high blood pressure treatment for more than a decade

- *A direct renin inhibitor, Rasilez is the first medicine to directly target the source of high blood pressure*
- *Alone or in combination with other medicines, Rasilez provides significant blood pressure lowering for 24 hours and beyond¹⁻⁴*
- *Nearly half of adults in Europe's largest countries suffer from high blood pressure⁵, which can cause heart attack, stroke and death⁶*
- *Strong need for new therapies since nearly 70% of high blood pressure patients still not achieving treatment goals^{6,7}*

Basel, August 27, 2007 – Rasilez® (aliskiren), the first new type of high blood pressure medicine in more than a decade, has been approved for use in the European Union. Nearly half of all adults in Europe's largest countries, such as Germany, Italy and the UK, suffer from this potentially life-threatening condition⁵.

The European Commission approved Rasilez for the treatment of high blood pressure alone or in combination with other high blood pressure medicines, based on data from more than 7,800 patients in 44 clinical trials. The approval applies to all 27 EU member states plus Iceland and Norway.

“Rasilez is the first medicine to directly target high blood pressure at its source, the enzyme renin,” said Dr. Roland Schmieder, Professor of Medicine at the University of Erlangen-Nuremberg, Germany. “As doctors, our biggest challenge is getting blood pressure under control in the first place and then keeping it there. Because Rasilez works well alone or with other medicines, it shows good promise in helping patients, even those who haven't yet achieved control with other medicines.”

Experts estimate that nearly one billion people globally have high blood pressure and that nearly 70% of these people do not reach healthy blood pressure levels^{6,7}. As a result, they live at risk of complications like heart attack, stroke, kidney failure, blindness and death, creating a strong need for new high blood pressure therapies⁶.

Rasilez is the first in a new class of medicines called direct renin inhibitors. It acts by directly inhibiting renin, an enzyme that triggers a process that can lead to high blood pressure. This new medication received its first approval in March 2007 from the US Food and Drug Administration under the brand name Tekturna®, and has also been approved in Switzerland.

When used alone, Rasilez demonstrates greater blood pressure lowering than other commonly-used blood pressure medicines like angiotensin converting enzyme (ACE) inhibitors⁸ and the diuretic hydrochlorothiazide (HCT)⁹.

For patients already taking other medicines, but not at their blood pressure goal, Rasilez provides additional blood pressure lowering when added to existing therapy. This additional benefit is seen when Rasilez is added to ACE inhibitors¹⁰, angiotensin II receptor blockers (ARBs)³, calcium channel blockers (CCBs)¹¹ or HCT¹², while offering a placebo-like tolerability profile³.

Rasilez consistently lowers blood pressure for 24 hours and beyond^{1,2}. This is an important treatment consideration, because many high blood pressure medicines fail to work around the clock, especially during the early morning hours when blood pressure often surges.

“Direct renin inhibition is the only major innovation in treating high blood pressure for more than a decade,” said James Shannon, MD, Global Head of Development at Novartis Pharma AG. “Rasilez is the first approved medicine that helps patients reach their blood pressure goal by controlling the renin system. Novartis is proud to bring this important new medicine to the fight against this damaging and rapidly increasing disease.”

The long-term potential of Rasilez and direct renin inhibition is being studied in a clinical program known as ASPIRE HIGHER, focusing on the benefits of using Rasilez in high blood pressure patients with heart failure or kidney failure. Data from the program are expected to be released later this year.

High blood pressure – and its consequences – is the world’s No. 1 cause of death. This condition, also called hypertension, occurs when the blood in the body moves through the blood vessels at a higher pressure than normal and causes damage to the arteries, kidneys, brain and other vital organs that can ultimately lead to heart failure.

Rasilez was developed in collaboration with Speedel.

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