

## **Press Release**

## Success in Patent Dispute Regarding Blood-Pressure-Lowering Drug: STADA Introduces Amlodipine/Valsartan Generic

- STADA wins dispute against Novartis before the European Patent Office (EPO).
- Generic active ingredient combination will be launched in numerous European STADA markets in the coming days, including Germany.
- CEO Peter Goldschmidt: "Important addition to our portfolio of blood-pressure-lowering drugs."

Bad Vilbel, March 20, 2019 – The STADA Group will be one of the first manufacturers to launch generic amlodipine/valsartan products, following the revocation of Novartis's European patent. After the sales launch in Spain, numerous other STADA subsidiaries will launch the active ingredient combination in their markets, including Germany.

"Amlodipine/valsartan is an important expansion of our portfolio of blood-pressure-lowering drugs and will make a positive contribution to our sales growth in 2019," says CEO Peter Goldschmidt, explaining the role of the product for STADA. Dr. Şenay Has, Vice President Intellectual Property at STADA and in charge at STADA in the dispute before the European Patent Office, adds: "The introduction of this product is a prime example of both the strategic vision and the agility within our Group. We recognized the opportunity of the patent's invalidity early on, challenged it in June 2016, ultimately brought the patent down, and now made everything possible quickly, so that we were ready to deliver immediately after the decision of the European Patent Office."

The EPO decided last Monday, March 11, 2019, that the European Patent EP 2 322 174 of the original manufacturer Novartis, which protected the active ingredient combination amlodipine/valsartan, had been wrongly granted and consequently revoked it. Novartis has previously been selling the active ingredient combination exclusively under the name Exforge<sup>®</sup>.



According to the World Health Organization (WHO), every third adult worldwide is suffering from high blood pressure, with the risk increasing with age. This makes the cardiovascular disease one of the most widespread lifestyle diseases of all. With the earliest possible launch of a generic amlodipine/valsartan alternative, STADA is therefore also making an important contribution to the healthcare of affected patients in Europe. They now have an equivalent but more affordable alternative to the original product available to them.

## **About STADA Arzneimittel AG**

STADA Arzneimittel AG is a publicly-listed company with headquarters in Bad Vilbel, Germany. The company focuses on a two pillar strategy consisting of generics, including specialty pharmaceuticals and non-prescription Consumer Health products. Worldwide, STADA Arzneimittel AG sells its products in approximately 130 countries. In financial year 2018, STADA achieved adjusted Group sales of Euro 2,330.8 million and an adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) of Euro 503.5 million. As of December 31, 2018, STADA employed 10,416 people worldwide.

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<sup>&</sup>lt;sup>1</sup> http://www.euro.who.int/en/about-us/whd/past-themes-of-world-health-day/world-health-day-2013-focus-on-high-blood-pressure/about-hypertension