



PRESS RELEASE

AIFA and FDA CONFIRM THE HIGH QUALITY STANDARD OF THE CAPUA FACILITY

SAUDI ARABIA AND SUDAN AUTHORISE THE CAPUA FACILITY FOR THE PRODUCTION OF MEDICINES DESTINED FOR THE MIDDLE EAST AND SUB SAHARA

Capua, 16 June 2015 – **Pierrel S.p.A.** (“Pierrel” or the “Company”) has been notified by the **Agenzia Italiana del Farmaco** (“AIFA”) that on 9 June last it formally renewed the authorisation for the production of pharmaceutical specialties made in Capua (CE) and destined for sale on the European market and in markets with mutual recognition.

The AIFA authorisation– that as a rule renews its consent every two years – follows a similar one received on 19 November 2014, from the Food & Drug Administration (“FDA”), the authority that regulates the admission of food and pharmaceutical products to the American market. The FDA, by confirming the high quality standard of the Capua facility, had also renewed the authorisation to produce and sell on the American market produced on the Pierrel site, amongst which is Orabloc®.

Toni Valente, CMO General manager of the facility, stated: *“To the authorisations that were renewed, and to those which are already available in Saudi Arabia – valid for all Middle East markets- we added also the authorisation of the Health Ministry of Sudan, that recently inspected the Capua site, and considered it ideal for the production of specialty medicines destined for the promising markets of sub Sahara. Such influential and prestigious recognition represent the just rewards for continuous improvement of the production systems carried out in the historical operations of Capua and constitute a sound base to continue the development plan of the company”.*

Pierrel continues thus to represent one of the few Italian companies, with a production unit in Italy, authorised to produce injectable drugs for sale in five continents Asia, Africa, Oceania, Europe and America, and is certainly the only one to have the authorisation to sell products under their own brand – such as Orabloc® - in North America.

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Pierrel S.p.A. is a global supplier to the pharmaceutical, biopharmaceutical and life science industries, specialising in the discovery of medicinal product candidates and the repositioning of existing drugs for new therapeutic indications and clinical research (TCRDO Division), pharmaceutical production (Contract Manufacturing Division) and the development, registration and licensing of new drugs and medical devices (Pharma Division).

Pierrel Group is listed on the MTA exchange which is organised and managed by Borsa Italiana and boasts over 60 years’ experience in the pharmaceutical sector, being one of Europe’s leading producers of local and dental anaesthetics. The TCRDO Division, working across Europe and the US, is recognised internationally for its research and development into tech based clinical research innovations with its Drug Repositioning and Repurposing System (“DRR2.0”) and Integrated Clinical Development Services (“ICDS”) for the pharmaceutical, biotechnology and biomedical industries. The parent company of the TCRDO Division (**THERAMetrics holding AG**, listed in the Swiss stock exchange) holds the innovative interactive **DRR2.0** platform, which runs on a database of 24 million scientific publications (being virtually all of those available in the field of biomedical literature), of over 4,900 drugs and of 9,400 illnesses. With this data, never before collected in one place and stored in the cloud, the Search and Match algorithm can show a researcher not only the candidate drug but also a detailed road map with indications of possible second medical uses. The database can be searched by molecule or by illness. Pierrel also has a production unit in Capua, close to Naples, Italy, that has been authorised by the European Medicines Agency (EMA) and the Food and Drug Administration (FDA) for the aseptic production of injectable medicines. The subsidiary Pierrel Pharma S.r.l. has registered and distributes the Orabloc® dental anaesthetic in Canada, US, Russia and Europe.

The registered office of Pierrel S.p.A. is in Capua (CE), Italy.



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