



PRESS RELEASE

SMILE (DIAGNOSTIC KIT FOR THE DIAGNOSIS OF CARIES): FIRST SAMPLES FROM THE ONGOING CLINICAL TRIALS UNDER STUDY

UBIGEL: CLINICAL TRIAL STARTED FOR GEL TO CURE PERIODONTITIS

PIERREL SINGLE-USE INJECTORS ARE STARS AT THE 2016 EXPODENTAL MEETING IN RIMINI

Capua, 23 May 2016 – Research and Development: these are the watch words guiding **Pierrel S.p.A.**'s industrial programme, which, through its Contract Manufacturing division (“CMO”) and its subsidiary **Pierrel Pharma S.r.l.** (the “**Company**”), aims to close 2016 with gross revenues of around €15.9 million and positive consolidated EBITDA of approximately €0.5 million, as reflected in the business plan approved on 20 April this year.

In particular, **Pierrel Pharma**, a wholly owned subsidiary of Pierrel S.p.A. dedicated to the development, registration and licensing of new drugs and medical devices, is quickly moving forward with the clinical trials of two new products: the **SMILE** kit, based on the levels of the soluble protein “sCD14” in saliva and intended for the diagnosis of dental caries, and **UBIGEL**, the medical and pharmacological device that helps restore and regenerate gingival mucosa in patients with periodontitis, **both scheduled to go on sale in 2017.**

In fact, Pierrel Pharma is pleased to announce that **UBIGEL** has entered the clinical trial phase, while for **SMILE** the ongoing clinical trial has enabled the collection of a large number of samples.

With **SMILE** and **UBIGEL**, the Company plans to repeat the market and global success achieved by its dental anaesthetics, headed by **Orabloc®**, the articaine for dental use produced under aseptic conditions in the plant in Capua (CE), Italy. A drug that achieved a 35% rise in sales in the North American market in the first quarter of 2016, compared to the same period of 2015, with record sales in March, up 42% from 2012, the year it was launched on the overseas market.

Pierrel dental anaesthetics were the stars of the EXPODENTAL MEETING 2016, the most important event for the industry in Italy and one of the top events in Europe. As the only anaesthetics manufacturer present, the company presented dentists its latest device, the **SINGLE-USE INJECTOR**, the first and only completely safe device for both the patient and the dentist, which meets the legal requirements (US 2000 EU 2010 EN 2013) on prevention and safety for accidental injuries from potentially contaminated needles. The injector is preloaded with a vial of Pierrel dental anaesthetic and accordingly comes under the category of combination products, i.e. devices that combine a drug with a medical device that enables its use.

Fabio Velotti, CEO of Pierrel Pharma S.r.l. stated: *“The interest from Italian and foreign professionals in our single-use injectors has by far exceeded our expectations. A confirmation that the device, which is the result of our own research and development, has very large scope for business development due to its complete safety, ease of use and sustainability.”*

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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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