



## PRESS RELEASE

### THE FOOD AND DRUG ADMINISTRATION (FDA) HAS AUTHORISED THE SALE OF GOCCLES IN THE NORTH AMERICAN MARKET

Capua, 18 September 2015 – **GOCCLES** (“Glasses for Oral Cancer – Curing Light Exposed – Screening”) – the revolutionary glasses for the early screening of pre-cancerous lesions in the oral cavity owned by **Pierrel Pharma S.r.l.** (the “Company”) is ready to be launched in the United States of America.

Today the **Food and Drug Administration** (“FDA”) – the US agency that deals with food and pharmaceuticals – authorised the sale and distribution in the US of GOCCLES, a device invented by the **Università Cattolica di Roma**, that is produced and sold by **Univet Optical Technologies S.r.l.** – a company that specialises in the design, production and marketing in over 50 countries worldwide of devices for the individual protection of eyes and optical magnifying systems for use in surgery and dentistry.

**Pierrel Pharma** specifically highlights the features of this further success:

- (i) The deadline announced to the market on 11 February 2015, which aimed to obtain the FDA authorisation for GOCCLES by the autumn 2015, was not only met, but achieved early;
- (ii) With the FDA authorisation for GOCCLES, Pierrel now boasts the presence of a second product approved in the US for dental care professionals that, thanks to Orabloc®, could experience the innovative content that the Company delivers to the leading edge of dental practice;
- (iii) GOCCLES has all the features to repeat the success of Orabloc® in the United States. The device, in fact, fully meets the needs of a market in which the culture of prevention of oral cancer is achieved through the practice of dentistry. In the US, for that matter, the process of change taking place in the dental profession, increasingly oriented towards changing dental surgeries into centres for prevention and oral health, is rapidly spreading.

Fabio Velotti, the sole Director of Pierrel Pharma, stated: “*The FDA authorisation enables the Company to accelerate the sale of GOCCLES in North America where initial positive signals are coming for the device that is produced and sold by Univet. In Univet we identified the partner with whom to share the passion for the international development of innovative products to be enhanced through time to market, flexibility, ability to engage with the customer and a constant physical presence in the country*”.

Paolo Portesi, CEO of Univet, the company entrusted with the licence and the industrial production of GOCCLES, commented on the news: “*...I am particularly pleased by the fact that GOCCLES has received, among other things, ahead of the estimated time, the approval by the FDA. The partnership between Pierrel Pharma and Univet is, on this occasion, more and more strategically successful and complementary. The American market leads, due to its size, for the attention to the prevention of oral cancer, and for its ability to create awareness and to attract attention to specific topics, also in other countries. We are confident that the approval of the FDA will be the first step towards a rapid build up of sales of GOCCLES across the whole of North America also together with the combined action of marketing, customer assistance and technical support that our New York subsidiary can provide*”.

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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.

**Univet Srl**, global industry manufacturer of Personal Protective Equipment (PPE), is an operator with twenty years experience in the sector of safety glasses. Univet srl operates with the PPE, laser, military and loupes (optical magnification systems destined for surgery and dental use) divisions.

Univet Srl has a worldwide presence in over 50 countries with its own offices and specialized distributors and is among the key players in all the international markets for protection and dental care. Univet S.r.l. magnification systems for surgical and dental use are based on optical technology developed in-house. The company's loupes are technologically advanced, light and tailor made, developing high performance around quality of field of vision, brightness and comfort.

Ongoing research in the eye protection sector has enabled Univet Srl to introduce significant innovations: SOFT - PAD for improved ergonomics and comfort; **Univet advanced Double Coating** (UDC), to maximise the anti-scratch and anti-fog features of lenses; NEXXT, a technology design centre focusing on solutions that perfectly complement other protection devices; ZERONOISE, an innovative technical solution for the integrated use of eye protectors and ear protection.

The in-house laboratory, **Applied Research Laboratory** (ARLab), is a leading-edge laboratory used in the design and pre-certification according to the main European and US regulations. The production unit and laboratory are based in Rezzato (BS), Italy.

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