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## **Oncoinvent sets regulatory strategy for development of Radspherin®**

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Oncoinvent announced today that the regulatory strategy that will be used in the development of its lead product Radspherin® has been selected.

The company has previously communicated that there are two equally attractive commercialization options available for Radspherin®. Due to Radspherin®'s inherent product characteristics the company has the option of either developing Radspherin as a medical device, or as a medicinal product. In the past, development of medical devices in Europe has traditionally taken significantly less time and has cost less than the development of medicinal products, an advantage that Oncoinvent has been considering could potentially lead to a faster time to market in Europe for Radspherin®.

### **Changes to the regulatory requirements for European market access**

Requirements for medical devices are changing in the EU. The new Medical Devices Regulation and IVD Regulation that was published in 2017 will have a dramatic effect on the future medical device industry. One consequence of the new regulation is that clinical data requirements and clinical development times and costs for medical devices will become significantly longer and greater respectively by the year 2020.

Based on input from the FDA, the Norwegian Medicines Agency, the German Notified Body TÜV-SÜD, in addition to expert advice received in the areas of clinical development, regulatory approvals, and market access, the company has now made the decision to develop Radspherin® as a medicinal product



Oncoinvent CEO Jan A. Alfheim commented, "After thoroughly analyzing the potential risks and benefits of the two regulatory pathways for Radspherin<sup>®</sup> we have concluded that selecting a medicinal product regulatory strategy for the USA and Europe will have a limited impact on the necessary future development cost, while providing a greater market potential for Radspherin<sup>®</sup>. This decision will affect the start of our planned phase I clinical trials, which we now plan to start early next year. We have concluded that the company's decision best serves the interests of the company and our shareholders in the long term"

### **About Radspherin<sup>®</sup>**

Radspherin<sup>®</sup> is a novel alpha-emitting radioactive microsphere designed for treatment of metastatic cancers in body cavities. The radium-224 based therapeutic, Radspherin<sup>®</sup> has shown strong and consistent anticancer activity at doses being essentially non-toxic in preclinical studies. It is anticipated that the product can potentially treat several forms of metastatic cancer. The first clinical indication for Radspherin<sup>®</sup> will be treatment of peritoneal carcinomatosis originating from ovarian cancer. Peritoneal carcinomatosis is one of the most serious complications of gastrointestinal and gynecological malignancies.

### **About Oncoinvent**

Oncoinvent AS is a privately held Norwegian company based in Oslo, Norway. The company is committed to developing new innovative products to provide better treatment options to cancer patients.

The company's founders started Oncoinvent in 2010 with a view to designing better cancer treatments by applying known physical and chemical principles of selected novel materials in new ways to maximize their medical benefit while minimizing potential safety concerns. This approach has allowed the company to develop a rich pipeline and to explore multiple technological avenues before selecting a lead product candidate for preclinical testing.

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