News release
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Genosafe, the French CRO expert in the evaluation of quality, safety and efficacy of advanced therapy medicinal products, expands to develop its pharmaceutical activity

Created 20 years ago by AFM-Telethon and Genethon, Genosafe has developed a unique expertise in analytical testing in the preclinical and clinical studies and in the quality control of gene and cell therapy products. With an average of fifty customers worldwide per year, Genosafe is one of the leaders in the field and is expanding to develop its activities in the pharmaceutical field.

Located in France, Genosafe, a CRO specializing in advanced therapy medicinal products, was created to support the different development steps of these products, from research to marketauthorization. Today, with more than 50 employees and experts in the field, Genosafe evaluates the quality, safety and efficacy of advanced therapy medicinal products according to 3 regulatory quality standards: Good Laboratory Practices, Good Manufacturing Practices and Good Clinical Practices. This expertise is recognized through the multiple international collaborations in which Genosafe is involved, thanks to its know-how in immunology, vectorology and molecular biology:

➢ **To evaluate the toxicity and efficacy of advanced therapy medicinal products (biodistribution, monitoring of immune response, etc.) in preclinical settings**

➢ **To control the quality of gene or cell therapy products**

➢ **To evaluate the safety and efficacy of these products in clinical trials**

In 20 years, the CRO has contributed to nearly 90 clinical trials, analyzed nearly 30,000 preclinical samples (since 2008) and nearly 10,000 patient samples (since 2015). Genosafe now works with 50 clients around the world and is expanding with the construction of new laboratories that will double its capacity.

"*The inception of Genosafe in 2003 was a visionary decision by its founders Genethon, the non-for-profit gene therapy biotech, and its mother organization AFM-Telethon the largest patient organization in Europe. With the prospect that gene therapy would prove effective and available to a growing number of patients it was necessary to have a structure capable of supporting the development of projects from the bench to the drug. The company has grown step by step to become one of the international leaders in the field of quality control of gene therapy and patient monitoring ».* Serge Braun, President of Genosafe.

"Since its creation Genosafe has continued to grow and strengthen its expertise in the analytical field for the evaluation of innovative therapies, mainly developed for the treatment of rare diseases. In 2008, we received certification for Good Laboratory Practice for the first time. Since 2015, we have been performing bioanalyses in patients enrolled in clinical trials. Today, we are continuing our development with the construction of new laboratories to develop our activity in the pharmaceutical field. Carole Masurier, CEO of Genosafe.

Genosafe in numbers*:*

- 7 million turnover
- 50 customers per year (70% based at the international, including 40% in the United States)
- 750 drug samples analysed each year
- Contributed to nearly 90 clinical trials
- Nearly 30,000 preclinical samples analyzed since 2008
- Nearly 10,000 patient samples analyzed since 2015
- 760 m² of laboratories today and 2000 m2 of laboratories tomorrow

Discover Genosafe:

https://www.genosafe.com

Contact presse

Stéphanie Bardon – presse@afm-telethon.fr – 01.69.47.12.78