NANOSAFETY of different Nanomedicines and the potential of lipid and paramagnetic nanoformulations for certain research lines and therapeutic applications

Eusebio Gainza[1], Oihane Ibarrola[1], Angel Pozo[1], Marta Pastor[1], Silvia Villullas[1], Garazi Gainza[1], Enara Herran[1].

[1]BioPraxis Research AIE, Hermanos Lumière, 5. 01510, Miñano (Araba).

The impact of nanotechnology on the safety of new medicines has been widely investigated by the scientific community over the last years, being a strategic research area of Praxis Pharmaceutical S.A. In the last decades, the elaboration of different particles at the nanometric scale, such as nanostructured lipid nanocarriers (NLC) and magnetic iron oxide nanoparticles (MNP), has become a very important strategy to overcome different drawbacks of biomolecules, peptides and chemotherapeutics. The nanoformulation of different compounds and molecules achieves a higher efficiency to the treatments: permits the administration of lower doses of drug with the same therapeutic effect, decreases the toxicity of the drug, diminishes the number of doses per treatment and enhances patient compliance and quality of life. Nevertheless, the registration of these nanoformulations it is not easy and according with National Products Safety Agencies and EMA additional safety confirmations are needed. That is the reason why, in these years Praxis Pharmaceutical has been working actively in NLC and MNP nanosafety evaluation in the framework of different European and National projects with promising results in the nanosafety context.

In this way the company and R&D Unit of Group are also involved in Lipid, Peptides, Recombinant Proteins and Advanced therapies to treat different pathologies, obtaining promising results in cell lines, different animal models and clinical trials. Recently, we are focusing our efforts in two main activities:

• Nanomedicine up-scaling under GMP conditions: we are working on the scaling up of the manufacturing of the nanoformulations from milligram-scale laboratory up to multigram-scale production. This scaling up process aims to generate sufficient material for clinical and regulatory assays, under relevant quality and safety control at the different stages of the up-scaling process.

• Clinical trial preparation and performance: we are including the necessary preclinical parameter tests to design clinical treatment protocol, regulatory assays and the preparation of the Investigational Medicinal Product Dossier (IMPD).