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Evolution of cancer drug development and registration paradigms in light of the successes of immunotherapy

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For many decades, early and late stage drug development of anti-cancer drugs have been very much based on tumor sizes evolution. They registration was mostly based on survival increase, although the evolution of tumor sizes (PFS) were also taken into account. Early guidelines on anticancer drugs focused on conventional cytotoxic compounds. A first major revision was made in Europe in 2005 stressing on the PFS followed by a second in 2010 introducing among others, the notion of relative toxicity. In recent years, immunotherapy, especially anti immune-suppressive agents such as anti CTLA4 and anti PD1/PDL-1 antibodies have shown remarkable increases in survival whereas they have relatively limited impact on the classical tumor size parameters. In addition to these improvements, not only increases in survival but increase in percentages of cures re more and more observed with recent anti-cancer drugs. Finally, combination of anticancer drugs such anti-immunosuppressive agents and other anti-cancer drugs may more and more prove to be very beneficial in the future. Consequently, the paradigms of drug development (efficacy criteria for phase II, for instance) as well as the regulatory and registration requirements will further evolve. Such probable evolutions will be discussed.

Biography

Didier Coquoz has completed his PhD in Clinical Pharmacology. He has more than 20 years of experience as Pharma R&D Executive (VP R&D and CEO). He has been instrumental in the development/regulatory management from drug candidate up to phase III and registration of close to 30 biologics, monoclonal antibodies, peptides, cell-based therapeutics, NCEs of which 4 reached the market world-wide. He held positions as CEO and VP R&D on both sides of the Atlantic. He currently acts through Copexis S.A. as Chief Development Officer, Chief Regulatory Affairs and Chief Business Development Affairs for different biotech/mid pharma in Europe, mostly in immunology.

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