

Chair Introduction

Christopher A Bravery

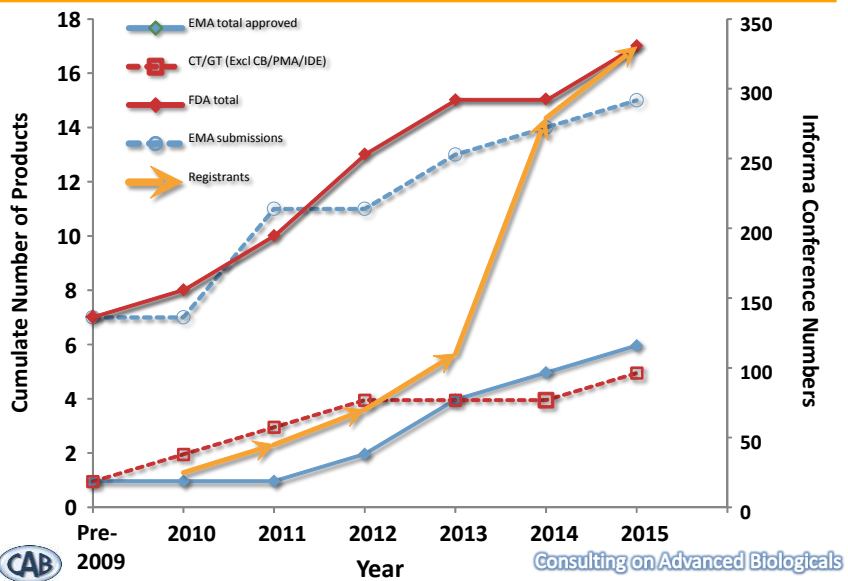
cbravery@advbiols.com

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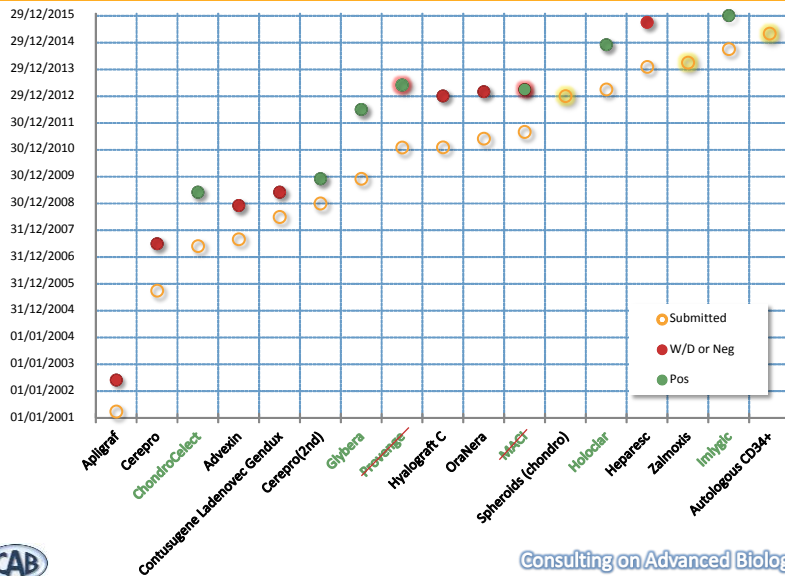
Consulting on Advanced Biologicals

Approvals: Where are we?



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Overall EU submissions and opinions



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Approvals – EU New since Dec 2014

Heparesc	Allogenic human heterologous liver cells	Allogenic human heterologous liver cells	Cytonet GmbH&Co KG	Feb 2014	Negative Re-exam July 2015	Negative Oct 2015
Imlygic	talmogene laheparepvec	treatment of adults with melanoma that is regionally or distantly metastatic	Amgen	Oct 2014	Positive Oct 2015	TBD
Zalmoxis	Allogenic T cells genetically modified to express suicide gene	treatment in haploidentical haematopoietic stem cell transplantation	MolMed SpA	Apr 2014	TBD	TBD
Undisclosed	autologous CD34+ cells transduced with retroviral vector containing the adenosine deaminase gene	for the treatment of severe combined immunodeficiency (SCID) due to adenosine deaminase (ADA) deficiency	Assumed/ GlaxoSmithKline	Est. May 2015	TBD	TBD

- ✓ One new approval, Imlygic (oncolytic virus, gene therapy)
 - ✓ Now 2 gene therapies in EU.
- ✓ Negative opinion for Cytonet (Heparesc)
- ✓ FDA also approved Imlygic (first gene therapy)
 - ✓ No other HCT/P since 2013

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Increases in ATMP Scientific Advice *CAT in-put on Scientific Advice*

Scientific advice procedures on ATMPs								
	2009	2010	2011	2012	2013	2014	2015	Total
Discussed*	25	30	36	31	36	48	58	269
Number of procedures	17	19	21	19	23	33	41	173

* Most scientific advices for ATMPs are discussed by the CAT at 2 time points during the SA procedure