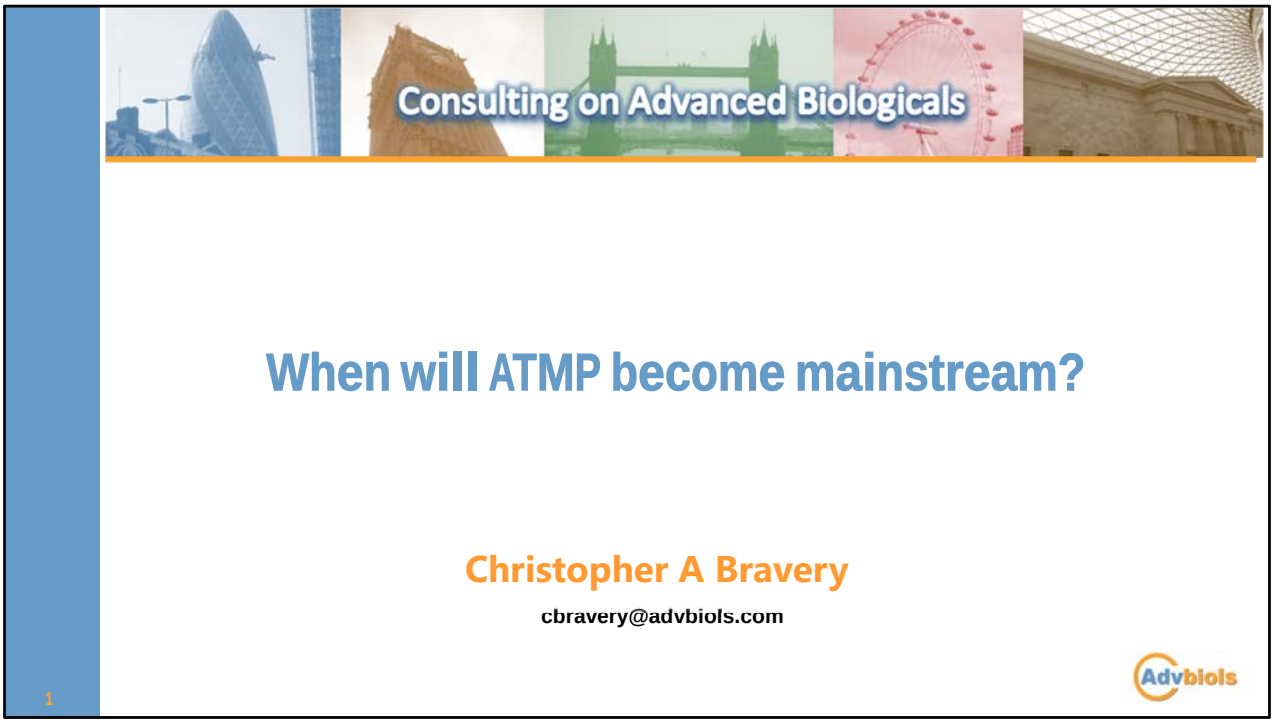

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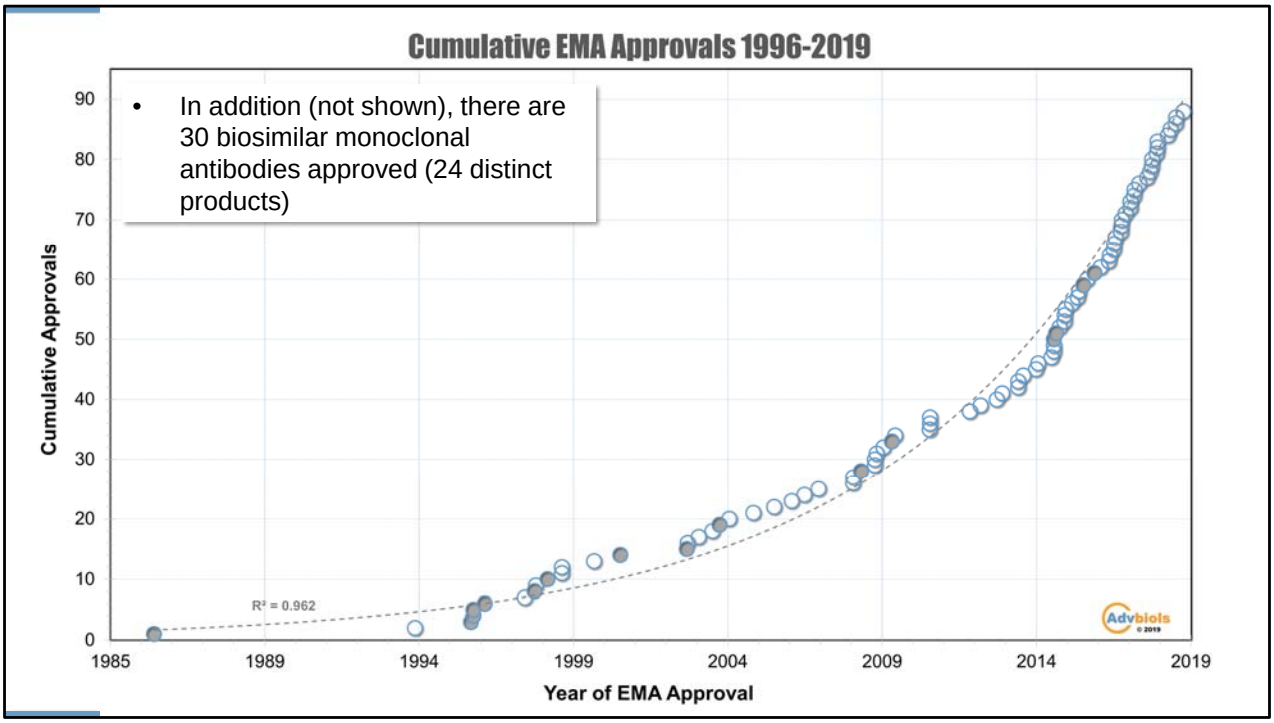
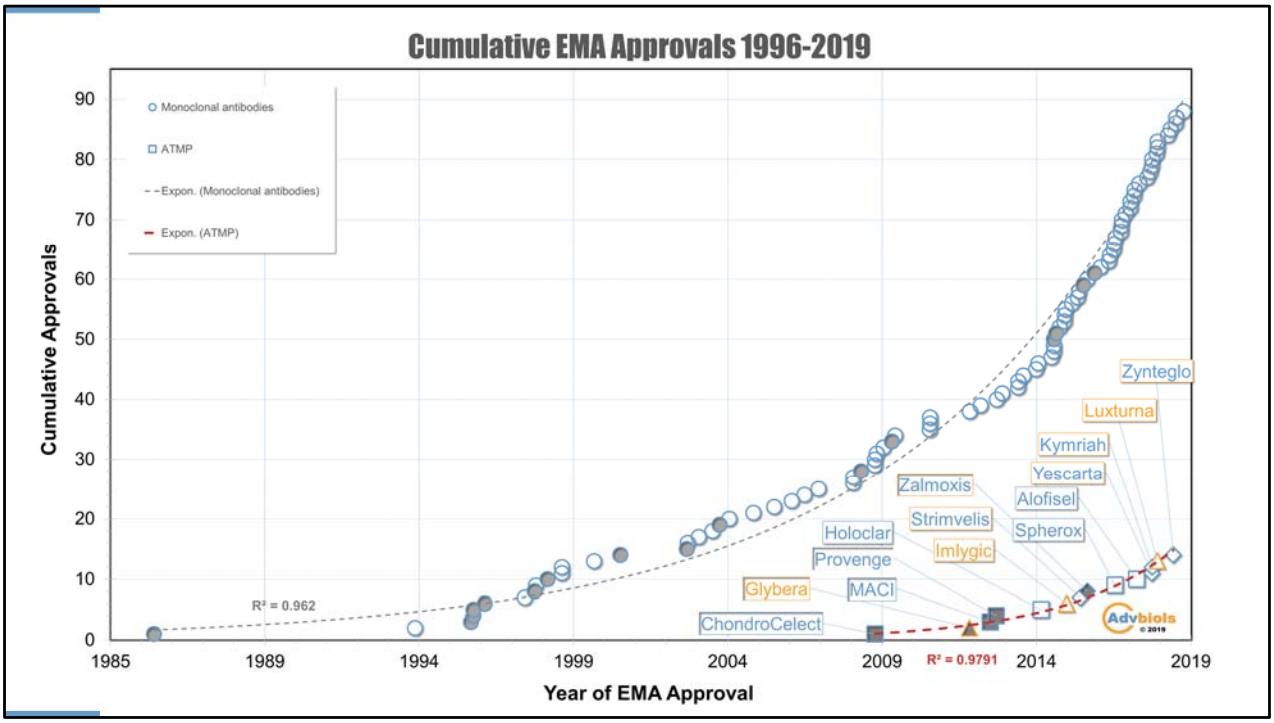
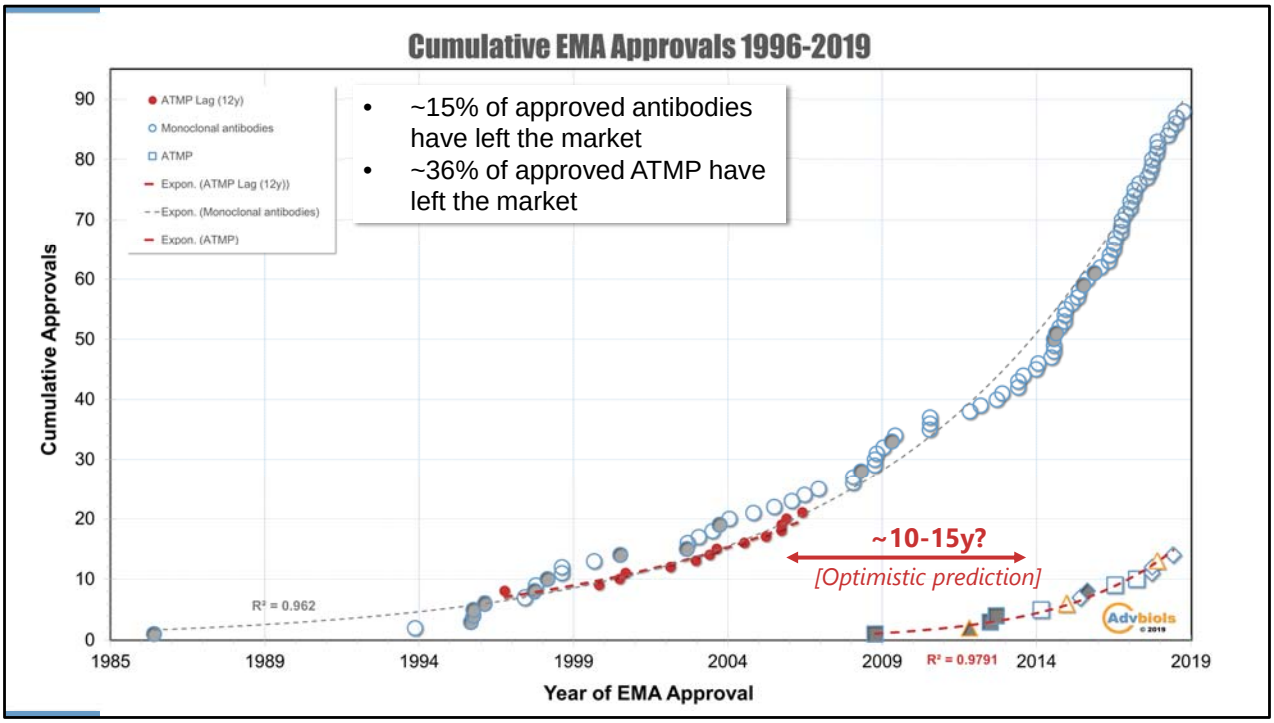


Mabs are now exponential with new mAbs approved every month, today ~90 (new active substances).
The biosimilars are not shown on this figure (not new active substances).
Empty circles, still marketed; grey filled circles, withdrawn after approval (but how long after not shown here).



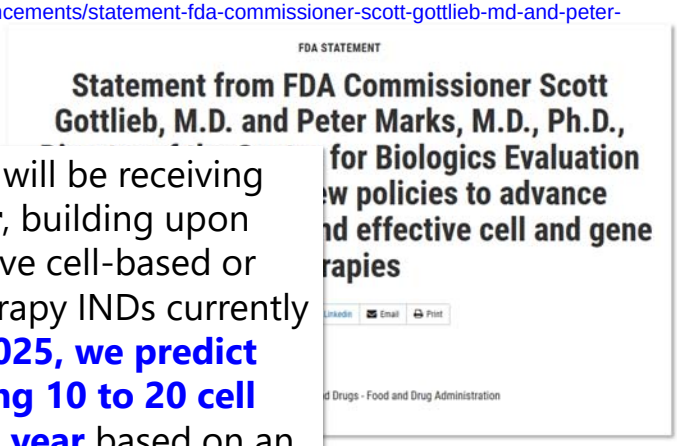
My own figure on cumulative mAb approvals and ATMP approvals – we are just at the start, will we mirror mAbs?
Mabs are now exponential with new mAbs approved every month, today ~90 (new active substances).
The biosimilars are not shown on this figure (not new active substances).
Empty circles, still marketed; grey filled circles, withdrawn after approval (but how long after not shown here).



I took the ATMP data and adjusted it back 12 years to find a match with mAbs.

REGULATORS ALSO NOTICING…

https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-peter-marks-md-phd-director-center-biologics


FDA STATEMENT

Statement from FDA Commissioner Scott Gottlieb, M.D. and Peter Marks, M.D., Ph.D., for Biologics Evaluation w policies to advance nd effective cell and gene rapies

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We anticipate that by 2020 we will be receiving **more than 200 INDs per year**, building upon our total of more than 800 active cell-based or directly administered gene therapy INDs currently on file with the FDA. And **by 2025, we predict that the FDA will be approving 10 to 20 cell and gene therapy products a year** based on an assessment of the current pipeline and the clinical success rates of these products.

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And the FDA recently predicted by 2025 (earlier than my prediction, which would be ~2030) they expect 10-20 ATMP to be approved per year; meaning roughly the number of mAbs approved currently per year by the EMA.