Welcome to your weekly digest of approaching regulatory and clinical readouts. Bristol-Myers Squibb and AbbVie’s multiple myeloma project elotuzumab is due to report phase III data in the first half of the year.

This asset carries substantial sellside forecasts, backed by breakthrough therapy designation in combination with Revlimid in refractory patients, and might be launched this year. Meanwhile, phase III results are expected for Exelixis’s Cometriq in the crowded indication of renal cell carcinoma, after earlier failing in prostate cancer.

**Elotuzumab: Bristol-Myers Squibb/AbbVie**

Consensus forecasts compiled by EvaluatePharma put elotuzumab’s 2020 sales at $1.2bn worldwide. In the US Bristol has a profit share with AbbVie.

The project received its second-line multiple myeloma breakthrough therapy designation last May. It is an antibody targeted against CS1, also known as SLAMF7, a glycoprotein found on myeloma cells but not detectable in normal tissue. It attaches to CS1 on the surface of myeloma cells and activates natural killer cells to target the cancer.

The phase III trial due to read out in the first half of the year is called Eloquent-2, and tests Revlimid and dexamethasone with or without elotuzumab in relapsed/refractory multiple myeloma. The study enrolled 640 patients, and the primary endpoints include progression-free survival and objective response rate. Overall survival is among the secondary measures.

A second trial, Eloquent-1, tests the combination in newly diagnosed, untreated patients. With an enrolment of 750 patients data could come next year. Phase III tests 10mg/kg, which was the lower of two doses used in a phase I/II study; the other was 20mg/kg.

In that earlier study in combination with Revlimid and dexamethasone overall the objective response rate was 84% and the median PFS was 29 months. The most common treatment-emergent adverse events were diarrhoea, muscle spasms and fatigue.

Elotuzumab is looking to become the first monoclonal antibody for use in multiple myeloma. With its breakthrough therapy designation a successful readout followed by a swift filing could see its launch this year (At least 11 future blockbusters await launch in 2015, January 21, 2015).

However, it will have to contend with another antibody, daratumumab, from J&J and Genmab. Although daratumumab’s phase III will not read out until late 2016, it too has breakthrough designation, and with full phase II expected at Asco a US regulatory filing this year is not beyond the realms of possibility (Genmab soars on hopes of early launch for novel myeloma drug, February 4, 2015).

**Cometriq: Exelixis**

Last September Exelixis shares plummeted by 55% when the group said the Comet-1 trial testing Cometriq in prostate cancer had failed, and 70% of its workforce was axed (Exelixis wiped out after Comet-1 crash lands, September 2, 2014). Cometriq is currently on the market in thyroid cancer, where last year it generated sales of just $25m.

Topline PFS data are expected in the second quarter of the year from the 650-patient Meteor trial testing Cometriq, known generically as cabozantinib, against Afinitor in second-line renal cell carcinoma. The study is 90% powered to detect a median PFS of 7.5 months for Cometriq, versus 5 months for Afinitor, a scenario that requires 259 of the first 375 patients randomised to have progressed.

The renal cell carcinoma market is increasingly crowded, with a number of multikinase inhibitors approved and anti-PD-1 agents on the horizon. Jefferies analysts believe that Cometriq has 70% odds of success in renal cancer with a potential launch next year, and model peak risk-adjusted revenues of $140m in this indication in
Exelixis says it has enough cash to last through this year, though given its hefty debt position the company desperately needs Cometriq to perform.

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