

AstraZeneca

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AstraZeneca and the art of resurrecting failed drug candidates

A year ago, AstraZeneca PLC's (LON:AZN) treatment targeting the autoimmune disease lupus crashed during phase III, a failure that was expected to bury the drug candidate.

Fast-forward to Tuesday and the pharma giant flipped the script, unveiling new data from a different study that now shows AZ's anifrolumab works.

If the intravenous medication goes to market, it'll be a big leap forward for lupus patients, who suffer from their own immune systems attacking healthy tissue, causing symptoms such as fatigue, skin rashes and weight loss.

Success may also act as a beacon of hope to two fledgling biotechs that have hit the buffers in a similar fashion to AZ - albeit at an earlier stage in the process.

Phase II trials from AIM-listed Mereo BioPharma Group PLC (LON:MPH) and Evgen Pharma PLC (LON:EVG) didn't meet their "primary endpoint". That's a jargon phrase that tends to denote failure and one that sends life sciences investors into a flap.

Evgen's shares immediately halved in value, while Mereo shed 28%.

What small biotechs can learn from AZ

Well, put bluntly, the Anglo-Swedish giant blamed the trial itself rather than the drug when it failed to negotiate the final-phase trial successfully.

So, it started again from first principles. AZ's initial phase III study required the drug to completely resolve one severe lupus symptom (such as seizures) or multiple milder ones while causing no new flares.

However, the second study decided to use a scale set by The British Isles Lupus Assessment Group for its Tulip 2 clinical assessment of anifrolumab.

This new standard required the drug improve disease activity across all affected organs, with no new flares.

Shore Capital analyst Tara Raveendran pointed out that this approach hasn't yet been used in a successful regulatory application. So, this may draw out the process of gaining approval from the US Food & Drug Administration (FDA).

Mereo merits hope

Moving down the evolutionary chain, Mereo BioPharma also appears to be looking at the clinical approach it took rather than at whether the drug has medical merit.

Okay, it failed to show an efficacious effect on increasing bone density in the wrists of patients with a rare bone disorder called osteogenesis imperfecta.

Price: 7675

Market Cap: £100.71 billion

1 Year Share Price Graph



Share Information

Code: AZN

Listing: LSE

52 week High Low
72750 109.511

Sector: Pharma & Biotech

Website: www.astrazeneca.com

Company Synopsis:

AstraZeneca is one of the world's leading pharmaceutical companies, with a broad range of medicines designed to fight disease. AstraZeneca has over 67,000 employees and operates in over 100 countries with growing presence in important emerging markets.

action@proactiveinvestors.com

However, setrusumab did appear to improve bone mineral density at the lumbar spine by blocking a protein called sclerostin, which stops bone-forming cells from doing their job.

Despite the trial's apparent stumble, Mereo still plans to go ahead with its pivotal paediatric study of 165 children aged between 5 and 18 years old, to see whether the drug can reduce bone fracture rates among brittle bone sufferers.

WATCH: Mereo BioPharma CEO confident as it moves forward with pivotal Setrusumab study
Going into the next trial, chief executive Denise Scots-Knight said the company is reviewing how it scans the bone for total growth since the phase IIb trial focused only on the wrists, an area of the body which only ever shows slight changes.

Scots-Knight found a ray of hope in the latest results, saying Mereo is "very very pleased" with the data, saying it achieved the phase II objective which was "to show that we have a very powerful bone-building effect, and to choose a dose for our pivotal study".

Evgen moves on

The smaller Evgen Pharma, meanwhile, has conceded it will scrap its drug SFX-01 as a treatment for a type of stroke known as subarachnoid haemorrhage after it did no better than a placebo in a phase II study.

Broker finnCap immediately sliced £14m off its valuation, while chief executive, Steve Franklin, said the firm was "surprised and disappointed" by the phase II findings. But there is still hope.

Evgen's treatment was based around Sulforadex, a version of the cancer-fighting compound sulforaphane that is found in brassica vegetables such as broccoli.

Other Evgen studies are testing its efficacy against different diseases, such as metastatic breast cancer, which means there's hope for the putative treatment yet.

So like AZ and Mereo's developments, there's another drug candidate that may well live to fight another day.

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