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## Compared to monotherapy combination of pills for advanced skin cancer extends survival

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The combination of cobimetinib and vemurafenib has been shown to extend the lives of previously untreated patients with advanced skin cancer to nearly two years (22.3 months) – an improvement of nearly five months more than the approved treatment, vemurafenib alone – according to new data from the coBRIM study presented at the Society for Melanoma Research (SMR) annual meeting (median overall survival 22.3 months compared with 17.4 months for vemurafenib alone (HR: 0.70; 95% CI: 0.55-0.90, P=0.005)).

These results are very promising; while progress has been made, there has been a great need to find new treatment options that can extend survival and reduce the likelihood of resistance – a common challenge in tackling this form of advanced skin cancer.

Cobimetinib and vemurafenib have complimentary ways of working together to block the cancer cell survival pathway, significantly extending life and could reduce or delay resistance. This is a very encouraging development."

Dr James Larkin, Consultant Medical Oncologist at The Royal Marsden and Lead Investigator of the Phase III study, coBRIM.

Cobimetinib works together with vemurafenib to target and block two parts of an important pathway involved in cancer cell growth and survival, called MAPK. The process can be likened to a canal system, with treatment acting as floodgates:

- Vemurafenib works by seeking out mutated BRAF proteins in the pathway and activating a floodgate blocking the 'survive and multiply' signals being sent directly into the cell.
- But, after time and in most cases when BRAF-inhibition treatment is given alone, resistance develops; the floodgate bursts or another route is found and the flow downstream is re-established.
- Cobimetinib works alongside vemurafenib to create a more powerful floodgate system; seeking out another
  protein in the pathway called MEK located downstream, and activating another floodgate reinforcing the
  blockade, leading to inhibited cell growth and the creation of a more powerful resistance barrier

The safety profile of the cobimetinib-vemurafenib combination was consistent with safety data previously reported. The most common adverse events in the combination arm were diarrhea, rash, nausea, fever, sun sensitivity, liver enzyme abnormalities, elevated creatine phosphokinase (CPK, an enzyme released by muscles) and vomiting.

In September 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a Marketing Authorization for cobimetinib, intended for the treatment of unresectable or metastatic melanoma in combination with vemurafenib. Marketing Authorization is expected towards the end of 2015.

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<u>Virgo Health</u>	