Binimetinib plus encorafenib meets primary endpoint with statistically significant advantage on median PFS of 14.9 months versus 7.3 months for vemurafenib monotherapy. Additional PFS, ORR and durability data support primary endpoint result

Detailed safety and drug exposure data presented; combination of binimetinib plus encorafenib demonstrates a favorable tolerability profile

Castres, France (November 9, 2016) -Pierre Fabre today announced first results from the pivotal Phase 3 COLUMBUS trial of
binimetinib
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encorafenib
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treatment
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BRAF
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mutant melanoma patients
at the Society for Melanoma Research
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The study met its primary endpoint, with the combination of
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significantly improving progression free survival (PFS) compared with
vemurafenib
, a BRAF inhibitor, alone.
The combination

of
bini
/
enco
was generally well-tolerated and reported adverse events
(AEs)
were overall consistent with previous
published
clinical trial results
f
or
the
bini
/
enco
combination in
BRAF
-mutant melanoma patients.

"The results presented today from the COLUMBUS trial including estimated progression free survival, objective response rate, dose intensity and tolerability of the combination provide a strong and consistent theme across multiple endpoints, underscoring the promise of binimetini b plus en corafenib as a potential, attractive treatment option for patients diagnosed with BRAF -mutant melanoma ," said Keith T. Flaherty, M.D., Director of the Termeer Center for Targeted Therapy, Massachusetts General Hospital and Professor of Medicine, Harvard Medical School.

In the analysis of the primary endpoint, the median PFS (mPFS) for patients treated with the combination of bini/enco was 14.9 months versus 7.3 months for patients treated with vemurafenib ; h azard ratio (HR) 0.54, (95% CI 0.41-0.71, p