Écrit par Pierre Fabre Mercredi, 09 Novembre 2016 21:21 - Mis à jour Mercredi, 09 Novembre 2016 21:31



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

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Castres, France (November 9, 2016) -Pierre Fabre today announced first results from the
pivotal Phase 3 COLUMBUS trial of
binimetinib
plus
encorafenib
bini
enco
treatment
in
BRAF
mutant melanoma patients
at the Society for Melanoma Research
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The study met its primary endpoint, with the combination of
bini
/
enco
significantly improving progression free survival (PFS) compared with
vemurafenib
, a BRAF inhibitor, alone.
The combination
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of
bini
/
enco
was generally well-tolerated and reported adverse events
(AEs)
were overall consistent with previous
published
clinical trial results
or
the
bini
/
enco
combination in
BRAF
-mutant melanoma patients.
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"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

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.

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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