### AML-12, AML-13, AML-16

Internal request to review the data and FDA label information for venetoclax in combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of newly-diagnosed AML in patients who are age 75 or older or who have comorbidities that preclude use of intensive induction therapy.

External request from AbbVie and Genentech requesting review of the updated and published data in patients with AML and the US Prescribing Information for venetoclax. On November 21, the FDA expanded the label and approved venetoclax in combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly diagnosed AML in adults who are age 75 or older or who have comorbidities that preclude use of intensive induction chemotherapy.

Based on a review of the supporting data and FDA label information, the Panel consensus was to add venetoclax in combination with azacitidine or decitabine for the treatment of the following indications:

- Candidate for intensive remission induction therapy
  - Unfavorable cytogenetic/molecular markers/
  - Antecedent hematologic disorder/
  - Therapy-related AML

Based on a review of the supporting data and FDA label information, the Panel consensus was to add venetoclax in combination with azacitidine, decitabine, or low-dose cytarabine for the treatment of the following indications:

- Not a candidate for intensive remission induction therapy or declines intensive therapy
- Post-remission therapy for patients treated with lower intensity therapy

### References

- See FDA Prescribing Information [www.fda.gov](http://www.fda.gov)
- See Submission for references.
Based on a review of the supporting data and FDA label information, the Panel consensus was to add glasdegib in combination with low-dose cytarabine for the treatment of the following indications:

- Not a candidate for intensive remission induction therapy or declines intensive therapy
- Post-remission therapy for patients treated with lower intensity therapy

References
- See FDA Prescribing Information [www.fda.gov](http://www.fda.gov)

Based on a review of the data and the FDA label information, the Panel consensus was to add gilteritinib for patients with relapsed/refractory disease and a FLT3 mutation.

References
- See FDA Prescribing Information [www.fda.gov](http://www.fda.gov)