Durvalumab : Adis Evaluation

Clinical Considerations

- A therapeutic fully human monoclonal antibody against PD-L1
- Significantly prolongs overall survival and progression-free survival compared with placebo when added to gemcitabine and cisplatin
- Manageable tolerability profile; most common adverse reactions included fatigue and gastrointestinal disorders

Plain Language Summary

Background and rationale

- Biliary tract cancers are a diverse group of cancers of the bile ducts or the gallbladder
- Patients with these cancers typically have poor survival
- Chemotherapy (gemcitabine plus cisplatin) has been the first-line treatment for biliary tract cancer for over a decade, with no new treatments improving on its overall survival benefit until recently
- Durvalumab (Imfinzi®) is part of a class of drugs known as checkpoint inhibitors; these drugs activate the immune system to help fight cancer

Clinical findings

- In the phase 3 TOPAZ-1 trial, the addition of durvalumab to first-line chemotherapy prolonged the overall survival compared with placebo plus chemotherapy in adults with advanced biliary tract cancer
- The tolerability of durvalumab in combination with chemotherapy was manageable

Conclusion

Durvalumab plus gemcitabine and cisplatin is a valuable new treatment option for patients with advanced biliary tract cancer