# A new ProTide, NUC-1031, combined with cisplatin for the first-line treatment of advanced biliary tract cancer (ABC-08)

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## Background

- **No prior systemic therapy for BTC**
- **Histologically verified cholangiocarcinoma**
- **Non-resectable or recurrent / metastatic**
- **Aged ≥ 18 years, ECOG PS 0 or 1**

## Results

### Efficacy Objective Response Rates in ABC-08 and ABC-02

<table>
<thead>
<tr>
<th></th>
<th>ABC-08</th>
<th>ABC-02</th>
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</thead>
<tbody>
<tr>
<td>Complete Response</td>
<td>9% (7/11)</td>
<td>5% (1/20)</td>
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<tr>
<td>Partial Response</td>
<td>43% (6/14)</td>
<td>25.5% (5/19)</td>
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<tr>
<td>Objective Response Rate</td>
<td>64% (7/11)</td>
<td>50% (9/18)</td>
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</tbody>
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### Conclusions

- **Encouraging ORR compared to SOC**
- **All subtypes sensitive to NUC-1031 + cisplatin**
- **Durable tumour shrinkage**
- **Promising survival outcomes in difficult to treat population**

## Objective

- **Safety**
- **RP2D**

## Methods

- **Cohort 1: 625 mg/m² NUC-1031 + 25 mg/m² cisplatin**
- **Cohort 2: 725 mg/m² NUC-1031 + 25 mg/m² cisplatin**
- **IV infusion on Days 1 and 8 of a 21-day cycle**
- **Treatment continued until tolerable toxicity or PD**

## Patient Population

- **Aged ≥ 18 years, ECOG PS 0 or 1, non-resectable or recurrent / metastatic**
- **BTC histologically verified**
- **Aged ≥ 18 years, ECOG PS 0 or 1**
- **Non-resectable or recurrent / metastatic**
- **Aged ≥ 18 years, ECOG PS 0 or 1**

## Pharmacokinetics

- **NUC-1031 + cisplatin generated stable and high levels of intracellular dFdCTP in patients’ peripheral blood mononuclear cells**
- **Intracellular dFdCTP levels were durable (mean half-life = 22 hours)**

## Conclusion

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**Study Design**

- **Primary Objectives**
- **Secondary Objectives**
- **Methods**
- **PK**

**Efficacy**

- **Objective Response Rates** in ABC-08 and ABC-02

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