Updates in Pharmacology

Elena Valcarlos, PharmD
Pharmacy Clinical Coordinator
Legacy Emanuel Medical Center
Portland, Oregon

Learning objectives

- To gain knowledge about new medications approved in the last 1-2 years that the medical/surgical nurse might encounter in practice
- Medications to be reviewed include new drugs for:
  - Infectious diseases
  - Heart failure
  - Diabetes

New Drugs for Infectious Diseases

Antibiotic pipeline problem

- Urgent need worldwide to develop new antibiotics to combat multi-drug resistant organisms
  - IDSA 10 x 20 Initiative
  - CDC’s Antibiotic Resistance Solutions Initiative
  - Transatlantic Taskforce on Antimicrobial Resistance
  - National Action Plan for Combating Antibiotic-Resistant Bacteria
  - WHO Global Action Plan for Antimicrobial Resistance

Zerbaxa™ (ceftolozane/tazobactam) injection

- Combination drug product containing a cephalosporin and beta-lactamase inhibitor
  - Broad spectrum coverage, including multi-drug resistant organisms
  - Limited gram positive coverage
  - Same class as: broad spectrum cephalosporins
- Approved for use in adults with:
  - Complicated intra-abdominal infections, when used in combination with metronidazole
  - Complicated UTI, including pyelonephritis
- Dose: 1.5 g IV in 100 mL NS or D5W infused over 1 hour q8h
- Side effects:
  - Nausea, diarrhea, headache and fever
  - Higher incidence of reactions in patients ≥65 yo
  - Avoid in patients with Zosyn allergy
  - No known drug-drug interactions
  - No known drug-lab interactions

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Zerbaxa™ (ceftolozane/tazobactam) injection

- Clinical efficacy – ASPECT cIAI:
  - Phase III, multinational, randomized, double-blind, double dummy non-inferiority trial
  - Zerbaxa™ + metronidazole vs. meropenem for 4-14 days
  - Favorable clinical response rates at test of cure visit:

<table>
<thead>
<tr>
<th>Population Analyzed</th>
<th>Zerbaxa™</th>
<th>Meropenem</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiologically modified ITT</td>
<td>83%</td>
<td>87.3%</td>
<td>-4.3% (9.2, 0.7)</td>
</tr>
<tr>
<td>Microbiologically evaluable</td>
<td>94.2%</td>
<td>94.7%</td>
<td>-0.5% (4.5, 3.2)</td>
</tr>
</tbody>
</table>
- Increased mortality in subset of patients with baseline creatinine clearance 30-50 mL/min

Zerbaxa™ (ceftolozane/tazobactam) injection

- Clinical efficacy – ASPECT cUTI:
  - Phase III, multinational, randomized, double-blind, double dummy non-inferiority trial
  - Zerbaxa™ vs. levofloxacin for 7 days
  - 26.5% resistance rate to levofloxacin at baseline
  - Favorable clinical response rates at test of cure visit:

<table>
<thead>
<tr>
<th>Population Analyzed</th>
<th>Zerbaxa™</th>
<th>Levofloxacin</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiologically modified ITT</td>
<td>76.9%</td>
<td>68.4%</td>
<td>8.5% (2.3, 14.6)</td>
</tr>
<tr>
<td>Levofloxacin resistant</td>
<td>80%</td>
<td>39.3%</td>
<td></td>
</tr>
<tr>
<td>Levofloxacin susceptible</td>
<td>82.6%</td>
<td>79.7%</td>
<td></td>
</tr>
<tr>
<td>Microbiologically evaluable</td>
<td>83.3%</td>
<td>75.4%</td>
<td>8.0% (2.0, 14.0)</td>
</tr>
</tbody>
</table>

Avycaz™ (ceftazidime/avibactam) injection

- Combination drug product containing a cephalosporin and beta-lactamase inhibitor
- Broadgram negative coverage, including multi-drug resistant organisms
- No gram positive coverage
- Same class as: broad spectrum cephalosporins
- Approved for use in adults with:
  - Complicated intra-abdominal infections, when used in combination with metronidazole
  - Complicated UTI, including pyelonephritis

Avycaz™ (ceftazidime/avibactam) injection

- Dose: 2.5 g IV in 50-250 mL NS or DSW over 2 hours q8h
- Side effects:
  - Common: vomiting, nausea, constipation, anxiety
  - Increased risk with renal impairment: seizures, encephalopathy, coma, asterixis, mydriasis
- Drug-drug interactions: no significant interactions
- Drug-lab interactions: ceftazidime causes false-positive reaction for glucose in urine with certain lab tests

Avycaz™ (ceftazidime/avibactam) injection

- Clinical efficacy:
  - Phase II, prospective, randomized, multicenter, double-blind, active controlled trial in complicated intra-abdominal infection
  - Avycaz™ + metronidazole vs. meropenem for 5-14 days
  - Favorable clinical response rates at test of cure visit:

<table>
<thead>
<tr>
<th>Population Analyzed</th>
<th>Avycaz™</th>
<th>Meropenem</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiologically modified ITT</td>
<td>82.4%</td>
<td>88.8%</td>
<td>-6.4% (23.8, 6.0)</td>
</tr>
<tr>
<td>Microbiologically evaluable</td>
<td>91.2%</td>
<td>93.4%</td>
<td>-2.2% (20.4, 12.2)</td>
</tr>
</tbody>
</table>

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)

These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Avycaz™ (ceftazidime/avibactam) injection
- Clinical efficacy:
  - Phase II, prospective, randomized, multcenter, double-blind trial in complicated UTI
  - Avycaz™ vs. imipenem for 7-14 days
  - Favorable microbiological response rates at test of cure visit:

<table>
<thead>
<tr>
<th>Population Analyzed</th>
<th>Avycaz™</th>
<th>Imipenem</th>
<th>Treatment Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Microbiological intention-to-treat (ITT)</td>
<td>67.4%</td>
<td>63.3%</td>
<td>4.1% (17.1, 25.4)</td>
</tr>
<tr>
<td>Microbiologically evaluable</td>
<td>70.4%</td>
<td>71.4%</td>
<td>-1.1% (-27.2, 25.0)</td>
</tr>
</tbody>
</table>

Zerbaxa™ & Avycaz™
- Advantages compared to other cephalosporins:
  - Activity against multi-drug resistant Pseudomonas
  - Activity against multi-drug resistant Enterobacteriaceae
  - No drug-drug interactions
  - Safer in elderly populations than other agents used to treat multi-drug resistant organisms (e.g. chloramphenicol, polymyxin, colistin, aminoglycosides)

Sivextro® (tedizolid phosphate)
- Oxazolidinone antibacterial agent
  - Broadgram positive coverage, including MRSA
  - No gram negative coverage
  - Same class as:
    - Linezolid (Zyvox®)
  - Approved to treat acute bacterial skin and skin structure infections in adults
  - Dose: 200 mg daily for 6 days

Sivextro® (tedizolid phosphate)
- Available as tablet and powder for injection
  - PO – may be given with or without food
  - IV – given in 250 mL NS over 1 hour
    - Not compatible with divalent cations (e.g. Ca²⁺, Mg²⁺)
    - Susceptible to foaming if shaken
  - Side effects:
    - Common: nausea, headache, diarrhea, vomiting, dizziness
    - Rare: myelosuppression, peripheral and optic neuropathy

Sivextro® (tedizolid phosphate)
- Clinical efficacy:
  - ESTABUSH-1 trial:
    - PO tedizolid for 6 days compared to linezolid for 10 days
  - ESTABUSH-2 trial:
    - IV-to-PO tedizolid for 6 days compared to linezolid for 10 days
  - Early clinical response rates met non-inferiority in both trials:

<table>
<thead>
<tr>
<th>Trial</th>
<th>Tedizolid</th>
<th>Linezolid</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESTABUSH-1</td>
<td>79.5%</td>
<td>79.4%</td>
<td>0.1% (4.1, 6.2)</td>
</tr>
<tr>
<td>ESTABUSH-2</td>
<td>85.2%</td>
<td>82.6%</td>
<td>2.6% (3.0, 8.2)</td>
</tr>
</tbody>
</table>

Sivextro® (tedizolid phosphate)
- Potential – but as yet to be confirmed - advantages compared to linezolid:
  - Higher theoretical barrier to resistance by MRSA
  - May be less likely to cause serotonin syndrome
  - May cause less myelosuppression and neuropathy
  - May cause fewer GI side effects
  - Cost?

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
**Orbactiv™ (oritavancin) injection**

- **Lipoglycopeptide antibacterial agent**
- **Gram positive coverage, including MRSA**
- **No gram negative coverage**
- **Same class as:**
  - Dalbavancin (Dalvance™)
- **Approved to treat acute bacterial skin and skin structure infections in adults**
- **Dose:** 1200 mg in 1000 mL D5W IV over 3 hours x 1
  - Not compatible with NS
  - Not to be infused with other drugs

**Orbactiv™ (oritavancin) injection**

- **Drug – lab test interaction:**
  - Oritavancin binds to and prevents the action of phospholipid reagents used to activate coagulation in common coag lab tests
  - **Artificially prolongs the aPTT for up to 48 hours**
  - **Artificially prolongs the PT/INR for up to 24 hours**
  - Also expected to impact ACT test
- **Drug – drug interactions:**
  - Weak inhibitor of CYP 2C9 and 2C19 → warfarin interaction?
  - Weak inducer of CYP 3A4 and 2D6 → decreased efficacy of opioids, certain antipsychotics, common beta blockers?

**Orbactiv™ (oritavancin) injection**

- **Side effects:**
  - **Hypersensitivity (aka allergic) reactions**
  - **Usual onset < 1.2 days; median duration = 2.4 days**
  - **Question patient about prior allergic reaction to vancomycin**
  - **Provide supportive care**
  - **Infusion related reactions**
  - **Itching, hives, flushing**
  - **Slow or interrupt infusion**
  - **Common**
  - **Headache**
  - **Nausea and vomiting**
  - **Diarrhea**

**Orbactiv™ (oritavancin) injection**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Oritavancin</th>
<th>Vancomycin</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOLO 1</td>
<td>82.3%</td>
<td>78.9%</td>
<td>3.4%(-1.6, 8.4)</td>
</tr>
<tr>
<td>SOLO 2</td>
<td>80.1%</td>
<td>82.9%</td>
<td>-2.7%(-7.5, 2.0)</td>
</tr>
</tbody>
</table>

**Dalvance™ (dalbavancin) injection**

- **Lipoglycopeptide antibacterial agent**
- **Gram positive coverage, including MRSA**
- **No gram negative coverage**
- **Same class as:**
  - Oritavancin (Orbactiv™)
- **Approved to treat acute bacterial skin and skin structure infections in adults**
- **Dose:** 1000 mg followed 1 week later by 500 mg
  - IV in D5W over 30 minutes
  - Incompatible with NS
  - Not to be infused with other drugs

**Dalvance™ (dalbavancin) injection**

- **Side effects:**
  - **Hypersensitivity (aka allergic) reactions**
  - **Question patient about prior allergic reaction to vancomycin**
  - **Provide supportive care**
  - **Infusion related reactions**
  - **More common with rapid infusion (<30 minute duration)**
  - **Itching, hives, flushing, rash**
  - **Slow or interrupt infusion**
  - **Common**
  - **Nausea, headache, diarrhea**
  - **Elevation of ALT**

---

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)

These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Dalvance™ (dalbavancin) injection

- Clinical efficacy:
  - Evaluated in 2 identically designed, phase III, randomized, double-blind, double-dummy, multicenter, non-inferiority trials
  - Compared to vancomycin followed by oral linezolid for a total of 10-14 days
  - Clinical response rates met non-inferiority criteria:

<table>
<thead>
<tr>
<th>Trial</th>
<th>Dalbavancin</th>
<th>Vancomycin</th>
<th>Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>DISCOVER-1</td>
<td>83.3%</td>
<td>81.8%</td>
<td>1.5% (-4.6, 7.9)</td>
</tr>
<tr>
<td>DISCOVER-2</td>
<td>76.8%</td>
<td>78.3%</td>
<td>-1.5% (-1.75, 4.6)</td>
</tr>
</tbody>
</table>

Price Comparison – Gram Positive Agents

<table>
<thead>
<tr>
<th>Agent</th>
<th>Cost of One Dose (AWP)</th>
<th>Cost of 10-day Course of Therapy (AWP)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daptomycin§</td>
<td>600 mg = $1178, 600 mg = $1487</td>
<td>$4500, $5740</td>
</tr>
<tr>
<td>Tedizolid</td>
<td>200 mg = $1932, 200 mg = $2042</td>
<td>$3170, $3280</td>
</tr>
<tr>
<td>Vancomycin§</td>
<td>1000 mg = $110, 2000 mg = $21020</td>
<td>$250, $40000</td>
</tr>
<tr>
<td>Dalbavancin*</td>
<td>1000 mg = $35176, 500 mg = $1788</td>
<td>$336, $354</td>
</tr>
<tr>
<td>Oritavancin*</td>
<td>1200 mg = $3480, 1600 mg = $5000</td>
<td>$3480, $5000</td>
</tr>
</tbody>
</table>

*Not covered by insurance for inpatient use. *Dose calculated for 80 kg patient.
* Assumes Q2W dosing, does not include cost of trough levels.

Rapivab™ (peramivir) injection

- Influenza virus neuraminidase inhibitor
- Same class as:
  - Oseltamivir (Tamiflu*) → available as oral tablet and liquid
  - Zanamivir (Relenza*) → available as oral inhaler
- Approved for the treatment of acute uncomplicated influenza in adults (≥18 yo) symptomatic for no more than 2 days
- Dose = 600 mg in 100 mL IV over 15-30 minutes x1
- Compatible with NS, 1/2NS, LR, D5W
- Not to be infused with other drugs

Rapivab™ (peramivir) injection

- Side effects:
  - Common
    - Diarrhea
    - Elevations of ALT, BG, CPK, and/or neutrophils
  - Uncommon → reported during postmarketing experience
    - Steven's Johnson Syndrome, exfoliative dermatitis, rash
    - Hallucinations and abnormal behavior

Rapivab™ (peramivir) injection

- Timing of flu vaccine:
  - Inactivated vaccine → can be administered at any time relative to peramivir administration
  - Live attenuated vaccine → avoid for 48 hours after peramivir dose administered
- Clinical efficacy:
  - Reduces symptom duration
    (by approximately 21 hours compared to placebo)
  - Non-inferior to oseltamivir
  - Has not been shown to provide benefit in serious influenza disease requiring hospitalization

New Drugs for Heart Failure

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Entresto™ (sacubitril + valsartan) tablets

- Combination drug product containing an angiotensin II receptor blocker and a neprilysin inhibitor
  - Neprilysin = neutral endopeptidase
  - Neprilysin inhibition leads to increased natriuresis
- Approved for use in adults with chronic heart failure (NYHA Class II-IV) and reduced ejection fraction
- Used in place of an ACE inhibitor or other ARB

Entresto™ (sacubitril + valsartan) tablets

- Titrated to target dose = 97/103 mg PO BID
  - Starting dose: 49/51 mg PO BID
  - Modified starting dose: 24/26 mg PO BID
    - Not currently taking an ACE inhibitor or ARB or previously taking low doses of these agents
    - Severe renal impairment (CrCl <30 mL/min)
    - Moderate hepatic impairment
    - Double the dose at 2-4 weeks
- Can be administered with or without food

Entresto™ (sacubitril + valsartan) tablets

- Side effects:
  - Common:
    - Hypotension
    - Hypokalemia
    - Cough
    - Dizziness
    - Renal failure
    - Rare:
      - Angioedema
- Contraindications:
  - Concomitant use with ACE inhibitor
  - Concomitant use with aliskiren in patients with diabetes or renal impairment
  - History of angioedema with ACE inhibitor or ARB

PARADIGM-HF trial

- Entresto™ vs. enalapril
  - Multinational, randomized, double-blind
- Patient population:
  - NYHA II-IV with EF ≤40%
  - On maximum tolerated doses of beta-blockers and on an ACE inhibitor or ARB for at least 4 weeks

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Entresto™</th>
<th>Enalapril</th>
<th>Hazard Ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite of CV death or hospitalization for HF</td>
<td>21.8%</td>
<td>26.5%</td>
<td>0.80 (0.73, 0.87)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>CV death</td>
<td>13.3%</td>
<td>16.5%</td>
<td>0.80 (0.71, 0.89)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Hospitalization for HF</td>
<td>11.8%</td>
<td>15.6%</td>
<td>0.79 (0.71, 0.89)</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Corlanor® (ivabradine) tablets

- Hyperpolarization-activated cyclic nucleotide-gated channel blocker
  - Reduces the spontaneous pacemaker activity of the cardiac sinus node by inhibiting the If current
  - Heart rate reduction with no effect on ventricular repolarization or myocardial contractility
- Approved for adults with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤35%
  - Sinus rhythm
  - Resting heart rate ≥70 bpm
  - Maximum tolerated dose of beta-blockers or with contraindication to beta-blocker use

Corlanor® (ivabradine) tablets

- Titrate to target heart rate 50-60 bpm
  - Usual starting dose = 5 mg PO BID
  - Starting dose if baseline conduction defects or if bradycardia could lead to hemodynamic compromise = 2.5 mg PO BID
  - Maximum dose = 7.5 mg PO BID
  - Increase dose at 2-4 weeks
- Administered with food

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Corlanor® (ivabradine) tablets

- Side effects
  - Bradycardia
  - Hypertension
  - Atrial fibrillation
  - Luminous phenomena (phosphenes)
- Drug-drug interactions ➔ significant!
  - Ivabradine is primarily metabolized by CYP3A4
  - Increased levels with CYP3A4 inhibitors
  - Decreased levels with CYP3A4 inducers

SHIFT trial

- Ivabradine vs. placebo
  - Randomized, double-blind, placebo-controlled
- Patient population
  - Stable NYHA class II – IV heart failure
  - LVEF ≤ 35%
  - Resting heart rate ≥ 70 bpm

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Corlanor®</th>
<th>Placebo</th>
<th>Hazard Ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composite of CV death or hospitalization for HF</td>
<td>24.5%</td>
<td>28.7%</td>
<td>0.82 (0.75, 0.90)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>15.6%</td>
<td>20.2%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>8.9%</td>
<td>8.5%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Corlanor® (ivabradine) tablets

- BEAUTIFUL trial
  - Randomized, double-blind, placebo-controlled
  - Added ivabradine to conventional therapy
  - Patient population = stable CAD with left ventricular dysfunction [LVEF <40% ➔ mostly NYHA Class II and III]
  - No significant effect on primary composite outcome of CV death, first MI or first hospitalization for HF (HR 1.00, 95% CI = 0.91, 1.10)
    - Reduced frequency of hospitalization and coronary revascularization in patients with baseline heart rate ≥ 70 bpm
- SIGNIFY trial
  - Randomized, double-blind, placebo controlled
  - Added ivabradine to guideline recommended therapy
  - Patient population = stable CAD without clinical evidence of HF (NYHA Class I)
  - No Significant effect on primary composite outcome of CV death or MI (HR 1.08, 95% CI = 0.96, 1.20)

New Drugs for Diabetes

- Afrezza® (insulin human) inhalation powder
  - Human insulin manufactured via recombinant technology; adhered to carrier molecules
  - Faster onset but same duration of action as regular insulin
  - Faster onset but longer duration of action compared to lispro
  - Product:
    - Breath activated inhaler
    - Powder for inhalation in cartridges of 4 units, 8 units, 12 units
    - 1 inhalation dose/cartridge
    - *Of note: For higher insulin doses, multiple inhalations from different strength cartridges are needed

- Administration:
  - Inhaled orally at the beginning of the meal
- Side effects:
  - Common
    - Hypoglycemia, cough, throat pain
    - Black box warning for bronchospasm
  - Contraindicated in patients with asthma and COPD
  - Not studied in, so not recommended for, smokers
  - Must monitor FEV1: obtain at baseline, at 6 months, then annually
  - If FEV1 decreases by ≥20%, then switching to alternate therapy should be considered

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Inhaled insulin

- Clinical efficacy:
  - Studied in patients with Type 1 and Type 2 diabetes
  - Appears to be equivalent to subcutaneous rapid acting insulin
  - Appears as effective as, or more effective than, metformin, sulfonylureas, rosiglitazone
- Potential target patient populations:
  - True needle phobia
  - Conditions that limit suitable injection sites for subcutaneous insulin
  - Recurrent local complications of subcutaneous insulin (such as skin infections or skin contact allergies)

Farxiga® (dapagliflozin) tablets

- Sodium-glucose cotransporter 2 (SGLT2) inhibitor
  - Increases urinary glucose excretion
  - Causes osmotic diuresis
- Same class as:
  - Invokana™ (canagliflozin)
  - Jardiance™ (empagliflozin)
- Approved as an adjunct to diet and exercise to improve glycemic control in type 2 diabetes
- Dose: 5 or 10 mg PO every morning, taken with or without food

Farxiga® (dapagliflozin) tablets

- Side effects:
  - Genital candidiasis
  - Nasopharyngitis
  - UTI
  - Increase in LDL-C
  - Dehydration, hypotension
  - ? Bladder cancer
- Caveats:
  - Correct volume depletion prior to initiating therapy
  - Avoid use in patients with CrCl <60 mL/min
  - Caution: increased risk of hypoglycemia when used concurrently with insulin or sulfonylureas

Tanzeum® (albiglutide) injection

- Glucagon-like peptide-1 receptor (GLP-1) agonist
  - Augments glucose-dependent insulin secretion
  - Suppresses glucagon secretion
  - Delays gastric emptying
  - Promotes satiety
- Same class as:
  - Victara™ (lixisenatide)
  - Byetta™, Bydureon™ (exenatide)
  - Trulicity™ ( dulaglutide)
- Approved as adjunct to diet and exercise to improve glycemic control in type 2 diabetes

Tanzeum® (albiglutide) injection

- Dose: 30 or 50 mg SQ once weekly
  - At any time of day, with or without food
  - Administer dose in abdomen, thigh, or upper arm
  - Administer missed dose within 3 days
  - Available as single dose pen
- Side effects:
  - Common:
    - Diarrhea
    - Nasal
    - Injection site reactions
    - Cough
    - Arthritis
    - Weight loss
  - Rare:
    - Pancreatitis
    - ? Thyroid cancer

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
Tanzeum® (albiglutide) injection

- Effect on lowering HbA1c:
  - Superior compared to placebo, sitagliptin, and glimepiride
  - Inferior compared to liraglutide and pioglitazone

- Compared to liraglutide:
  - Less HbA1c reduction
  - Less weight loss
  - Fewer GI side effects

Trulicity™ (dulaglutide) injection

- Glucagon-like peptide-1 receptor (GLP-1) agonist
  - Augments glucose-dependent insulin secretion
  - Suppresses glucagon secretion
  - Delays gastric emptying
  - Promotes satiety

- Same class as:
  - Victoza™ (liraglutide)
  - Byetta™, Bydureon™ (exenatide)
  - Tanzeum® (albiglutide)

- Approved as adjunct to diet and exercise to improve glycemic control in type 2 diabetes

Trulicity™ (dulaglutide) injection

- Side effects
  - Common:
    - Nausea
    - Diarrhea
    - Vomiting
    - Abdominal pain
    - Decreased appetite
  - Rare:
    - Pancreatitis
    - ? Thyroid cancer

Type 2 diabetes management

First:
- Diet modifications, weight reduction, exercise and metformin

Next:
- Depends on HbA1c level at baseline, patient preference, cost of therapy and evidence of benefit
- GLP-1 agonists
  - not first line therapy
  - generally used as add-on therapy
  - may be used in combination with basal insulin
- SGLT2 inhibitors
  - not first line therapy
  - generally used as add-on therapy
  - appropriate patient selection is key

References

New drugs for infectious diseases:
2. Solomkin J, Lieninger E, et al. Ceftriaxone/aztreonam plus meropenem for complicated intra-abdominal infection: in an era of multidrug resistance: results from a randomized, double-blind, phase 3 trial (ASPECT-
3. Wagner KE, Im, et al. Ceftriaxone/tobramycin compared with levofloxacin in the treatment of complicated urinary tract infections, including pyelonephritis: a randomized, double-blind, phase 3 trial (ASPECT-
   2309.

Academy of Medical-Surgical Nurses (AMSN) 24th Annual Convention (2015)
These materials were specially prepared for instructional use by AMSN and remain the property of AMSN and/or individual presenters. No portion of these materials, in whole or part, may be used in any fashion, or reproduced by any means, without the written permission of AMSN and/or individual presenters.
New Drugs for Infection Disease:


New Drugs for Diabetes:


References

New Drugs for Infection Disease:


New Drugs for Diabetes: