# Merck KGaA Patient Finder Suitability Analysis

**Prepared for:** Ada Health Patient Finder Business Development
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**Analyst:** Ada Cockpit Research Division
**Format:** v4 (Market Numbers, Clinical Profile, Commercial Signals, PF Opportunity)

## Executive Summary

This analysis evaluates Merck KGaA's drug portfolio for Ada Patient Finder suitability. We assessed **8 major drugs** across oncology, neurology, and rare diseases, identifying **6 viable opportunities** with projected Year 2 USA revenue of **$34M-$43M**.

**3**
Tier 1 Drugs
(Pursue Aggressively)

**3**
Tier 2 Drugs
(Pursue)

**$34-43M**
Total Year 2
Ada Revenue (USA)

**9/10**
Top Fit Score
(Tepmetko, Erbitux HNSCC)

# Portfolio Summary Table

| Drug | Indication | Tier | Fit Score | Addressable Undiagnosed (USA) | Ada Revenue Opportunity (Year 2, USA) |
|---|---|---|---|---|---|
| **Tepmetko (tepotinib)** | **METex14 NSCLC** | **1** | **9/10** | **2,100 - 2,800 patients/year** | **$8.0M - $10.5M** |
| **Erbitux (cetuximab)** | **Head & Neck Squamous Cell Carcinoma** | **1** | **9/10** | **3,300 - 3,500 patients/year** | **$7.6M - $8.1M** |
| **Bavencio (avelumab)** | **Urothelial Carcinoma (Bladder Cancer)** | **1** | **8/10** | **1,260 - 1,600 patients/year** | **$10.2M - $12.9M** |
| **Bavencio** (avelumab) | Merkel Cell Carcinoma | **2** | **8/10** | 300 - 400 patients/year | **$6.5M - $8.6M** |
| **Erbitux** (cetuximab) | Colorectal Cancer | **2** | **7/10** | 400 - 650 patients/year | **$924K - $1.5M** |
| **Ogsiveo** (nirogacestat) | Desmoid Tumors | **2** | **7/10** | 90 - 180 patients/year | **$720K - $1.4M** |
| Mavenclad (cladribine) | Multiple Sclerosis | **NO** | **4/10** | 1,200 patients/year | NOT VIABLE (US generic March 2026) |
| Gonal-f (follitropin alfa) | Fertility / Ovulation Induction | **NO** | **2/10** | N/A (no diagnostic delay) | NOT APPLICABLE |

# 1. TEPMETKO (Tepotinib) - METex14 NSCLC

## Tier 1 | Fit Score: 9/10 | Market Expansion Play

| ADDRESSABLE UNDIAGNOSED (USA) | NET REVENUE PER PATIENT |
|---|---|
| **2,100 - 2,800/year** | **$150,473** |
| PF FEE PER PATIENT | YEAR 2 ADA REVENUE (USA) |
| **$12,038 - $18,057** | **$8.0M - $10.5M** |

## Key Insight

**Testing Gap = Market Expansion:** Fewer than 50% of advanced NSCLC patients receive the comprehensive NGS testing needed to identify METex14 mutations. This leaves 3,500-4,700 eligible US patients annually without access to targeted therapy—they default to suboptimal chemotherapy instead.

## Market Numbers

- **USA:** 235,000 annual NSCLC cases → 7,050-9,400 METex14 cases (3-4%) → 50% testing gap = 2,100-2,800 undiagnosed drug-addressable
- **DACH:** 63,265 NSCLC cases → 451-602 undiagnosed drug-addressable (40% testing gap, better than USA)
- **Rest of World:** 3,000-4,000 undiagnosed drug-addressable (focus: EU ex-DACH, Japan, Canada, Australia)
- **Current Market:** $142M globally (Tepmetko + Tabrecta); **Growth Potential:** $300-400M by 2030 if testing reaches 80%+

## Clinical & Diagnostic Profile

- **Symptoms:** Persistent cough (85%), hemoptysis (25-30%), dyspnea (60%), weight loss (40%); often asymptomatic until advanced
- **Diagnostic Delay:** Testing gap is primary barrier (not symptom-to-diagnosis delay); NGS results take 7-21 days when ordered
- **Common Misdiagnoses:** Pneumonia, COPD exacerbation, asthma, tuberculosis
- **Ada Surface Ability: 9/10** — Respiratory symptoms well-captured; two intervention points: (1) Pre-diagnosis: Flag for low-dose CT screening, (2) Post-diagnosis: Ensure NGS testing before chemo

## Commercial Signals

- **Launch:** FDA traditional approval Feb 2024 (accelerated 2021); revenue ramping slowly due to testing gap
- **Competition:** Tabrecta (Novartis) has 52% market share; Tepmetko differentiates with once-daily dosing vs BID
- **Company Motivation: 9/10** — Oncology is strategic priority post-Mavenclad cliff; CEO Kai Beckmann prioritizes growth businesses
- **Partnership Fit:** Merck seeks "diagnostic and patient identification platforms" — testing advocacy aligns perfectly

> ***Pitch Hook:*** *"Half of METex14 NSCLC patients never get tested—Ada can close that gap and grow the Tepmetko market by 50%. Our model projects $3-4M Year 1 Ada revenue, scaling to $8-11M Year 2 at 10-25% penetration, while expanding your $68M product into a $200M+ opportunity by 2028."*

# 2. ERBITUX (Cetuximab) - Head & Neck Cancer

## Tier 1 | Fit Score: 9/10 | Severe Diagnostic Delay

| ADDRESSABLE UNDIAGNOSED (USA) | NET REVENUE PER PATIENT |
|---|---|
| **3,300 - 3,500/year** | **$115,500** |
| PF FEE PER PATIENT | YEAR 2 ADA REVENUE (USA) |
| **$9,240 - $13,860** | **$7.6M - $8.1M** |

## Key Insight

**8+ Month Diagnostic Delay:** Head and neck cancer symptoms (persistent sore throat, hoarseness, neck lumps) get dismissed as infections, leading to median 8+ month delays (4-12 weeks even in developed markets). 65% of patients delayed >3 months. By the time of diagnosis, 30% present at advanced stages.

## Market Numbers

- **USA:** 55,000 annual HNC cases → 13,200-14,850 Erbitux-eligible (advanced/platinum-resistant) → 30% late-stage presentation due to delay = 3,300-3,500 undiagnosed drug-addressable
- **DACH:** 12,000-15,000 HNC cases → 860-1,350 undiagnosed drug-addressable
- **Rest of World:** 7,750-8,750 undiagnosed drug-addressable
- **Revenue:** Erbitux global €1.2B (2024), +15.7% growth despite biosimilars; USA ~$420M

## Clinical & Diagnostic Profile

- **Symptoms:** Persistent sore throat >3 weeks (60%), hoarseness (40%), dysphagia (50%), neck mass (50%), otalgia (referred ear pain, 30%)
- **Diagnostic Delay: 8+ months** (underserved regions), 4-12 weeks (developed); misattributed to pharyngitis, laryngitis, GERD, dental issues
- **Common Misdiagnoses:** Multiple antibiotic courses for "tonsillitis," voice overuse (hoarseness), dental abscess (mouth ulcer)
- **Ada Surface Ability: 9/10** — "Persistent sore throat >3 weeks" is textbook red flag; throat/voice/swallowing symptoms are Ada's strength

## Commercial Signals

- **Performance:** +15.7% growth (2024) despite core patents expired (US 2016, EU 2014); biosimilars in India, China, Russia
- **Strategy:** Volume growth (finding more patients) offsets biosimilar price erosion
- **Company Motivation: 8/10** — Mature product, but patient finding = differentiation vs biosimilars ("We find patients early and save lives")
- **Competition:** Keytruda gaining share in first-line; Vectibix (Amgen) splits EGFR market 50/50

> ***Pitch Hook:*** *"HNSCC patients wait 8+ months for diagnosis while symptoms get dismissed as infections—Ada can cut that delay in half and expand the Erbitux-eligible population. Year 1: $3.8-4M Ada revenue. Year 3: $11-14M at 30-35% penetration. This transforms Erbitux from a biosimilar-threatened product into a differentiated outcomes play."*

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# 3. BAVENCIO (Avelumab) - Urothelial Carcinoma

## Tier 1 | Fit Score: 8/10 | Highest Per-Patient Economics

| ADDRESSABLE UNDIAGNOSED (USA) | NET REVENUE PER PATIENT |
|---|---|
| **1,260 - 1,600/year** | **$1,080,000** |
| PF FEE PER PATIENT | YEAR 2 ADA REVENUE (USA) |
| **$86,400 - $129,600** | **$10.2M - $12.9M** |

## Key Insight

**UTI Misdiagnosis = Advanced Stage:** Bladder cancer presents with hematuria and urinary symptoms that mimic UTIs. Patients receive 2-4 antibiotic courses before cystoscopy, creating 78-82 day delays. This increases odds of muscle-invasive or metastatic disease by **28-42%**, pushing patients into the advanced Bavencio-eligible population.

## Market Numbers

- **USA:** 82,000 annual bladder cancer cases → 9,840 advanced UC Bavencio-eligible (post-platinum maintenance) → 15-20% UTI delay = 1,260-1,600 undiagnosed drug-addressable
- **DACH:** 9,600-12,000 bladder cancer → 170-220 undiagnosed drug-addressable
- **Rest of World:** 1,800 undiagnosed drug-addressable
- **Revenue:** Bavencio estimated $1-2B globally (not broken out separately); UC maintenance is key growth driver

## Clinical & Diagnostic Profile

- **Symptoms:** Hematuria (gross/microscopic, 80-90%), dysuria (30%), urinary frequency/urgency (40%), pelvic pain (20%)
- **Diagnostic Delay: 78-82 days** symptoms-to-surgery; multiple antibiotic courses before imaging
- **Common Misdiagnoses:** UTI (urinary symptoms + hematuria), kidney stones (hematuria), menstruation (women), prostatitis (men)

- **Ada Surface Ability: 8/10** — Hematuria and "recurrent UTI" pattern easily captured; key value is flagging UTI without positive culture for cystoscopy

### Commercial Signals

- **UC Maintenance:** FDA-approved first-line maintenance post-platinum chemo; real-world evidence supports durable responses
- **Competition: EXTREME** — Keytruda ($25B) and Opdivo ($8B) dominate; Bavencio's niche is UC maintenance defense
- **Company Motivation: 7/10** — Niche differentiation strategy; patient finding aligns with defending UC maintenance vs Keytruda
- **Economics:** Highest per-patient revenue in portfolio ($1.08M) justifies $86-130K PF fees

> ***Pitch Hook:*** *"Bladder cancer gets dismissed as UTI for months—Ada can stop that and deliver $6-9M Year 1 revenue with the highest per-patient economics in your portfolio ($86-130K PF fees). This defends Bavencio's UC maintenance niche against Keytruda by demonstrating superior patient outcomes: 'We find them early, before progression excludes them from therapy.'"*

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## 4. BAVENCIO (Avelumab) - Merkel Cell Carcinoma

### Tier 2 | Fit Score: 8/10 | Ultra-Rare, High-Value

| ADDRESSABLE UNDIAGNOSED (USA) | NET REVENUE PER PATIENT |
|---|---|
| **300 - 400/year** | **$1,080,000** |

| PF FEE PER PATIENT | YEAR 2 ADA REVENUE (USA) |
| --- | --- |
| **$86,400 - $129,600** | **$6.5M - $8.6M** |

## Key Insight

**The Great Masquerader:** MCC appears as innocuous skin nodules, mistaken for cysts or infections. <1% correctly suspected pre-biopsy, with >3 month diagnostic delays while aggressive cancer spreads lymphatically. 5-year survival <20% at advanced stages.

## Market Numbers

- **USA:** ~3,000 annual MCC cases → 1,650 metastatic/locally advanced → 20% delay = 300-400 undiagnosed drug-addressable
- **DACH:** ~460 MCC cases → 50 undiagnosed drug-addressable
- **Prevalence:** 0.7 per 100,000 (US), higher in elderly (>70%), immunocompromised, sun-exposed regions

## Clinical & Diagnostic Profile

- **Symptoms:** Rapidly growing, painless skin nodule (80%), red/purple/flesh-colored, firm, sun-exposed areas (head/neck 45-49%)
- **Diagnostic Delay: >3 months** nodule-to-biopsy; often "watch and wait" before dermatology referral
- **Common Misdiagnoses:** Epidermoid cyst, lipoma, abscess, seborrheic keratosis, basal cell carcinoma
- **Ada Surface Ability: 6/10** — Skin lesion assessment challenging without visual AI; risk factors (age >70, immunosuppressed) help

## Strategic Value

- **Company Motivation: 7/10** — Orphan drug, limited market size, but demonstrates rare disease expertise (aligns with SpringWorks acquisition narrative)
- **First-Mover:** Bavencio was first checkpoint inhibitor approved for MCC (2017); Keytruda approved 2018 but no clear efficacy advantage

> ***Pitch Hook:*** *"MCC is the great masquerader—misdiagnosed as cysts for months while it spreads. Ada can deliver $3.2-4.3M Year 1 revenue while demonstrating commitment to rare disease patient outcomes (aligning with SpringWorks acquisition narrative)."*

# 5. ERBITUX (Cetuximab) - Colorectal Cancer

### Tier 2 | Fit Score: 7/10 | Screening Gaps

ADDRESSABLE UNDIAGNOSED (USA)

**400 - 650/year**

NET REVENUE PER PATIENT

**$115,500**

YEAR 2 ADA REVENUE (USA)

**$924K - $1.5M**

## Key Insight

**Post-Colonoscopy Underdiagnosis:** Colonoscopy screening misses 2.5-7.7% of CRC cases (right-sided lesions, polyp morphology). Symptomatic patients wait 34-60 days for diagnosis while rectal bleeding gets attributed to hemorrhoids or IBS.

## Market Numbers

- **USA:** 160,000 annual CRC cases → 18,400-24,150 metastatic RAS wild-type → 3-5% underdiagnosis = 400-650 undiagnosed Erbitux-eligible
- **RAS Wild-Type:** 50-65% of metastatic CRC (EGFR therapy eligible)

### Clinical & Diagnostic Profile

- **Symptoms:** Rectal bleeding (50-60%), bowel habit changes (40%), abdominal pain (30%), weight loss (25%)
- **Diagnostic Delay: 34-60 days** symptom-to-diagnosis; false-negative colonoscopy (2.5-7.7%)
- **Ada Surface Ability: 7/10** — GI symptoms well-captured; rectal bleeding is red flag; high false-positive rate (hemorrhoids, IBS)

### Commercial Context

- **Maturity:** CRC indication is mature, lower priority than HNSCC
- **Company Motivation: 6/10** — Patient finding can offset biosimilar erosion but limited upside vs other indications

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## 6. OGSIVEO (Nirogacestat) - Desmoid Tumors

### Tier 2 | Fit Score: 7/10 | SpringWorks Integration KPI

ADDRESSABLE UNDIAGNOSED (USA)

**90 - 180/year**

NET REVENUE PER PATIENT

**$200,000**

YEAR 2 ADA REVENUE (USA)

**$720K - $1.4M**

### Key Insight

**CEO Priority Asset:** Merck acquired SpringWorks for $3.9B (July 2025), making Ogsiveo integration success a critical KPI for CEO Kai Beckmann's first major M&A. Desmoid tumors dismissed as benign lipomas/fibromas for 12-24 months before specialist referral.

## Market Numbers

- **USA:** 900-1,500 annual desmoid cases → 450-900 progressive/symptomatic (Ogsiveo-eligible) → 20% delay = 90-180 undiagnosed
- **Rarity:** 2.7-4.5 per million incidence; often associated with FAP (familial adenomatous polyposis)
- **Revenue:** Ogsiveo $172M (2024); analyst peak >$1B by 2030

## Clinical & Diagnostic Profile

- **Symptoms:** Slowly growing, painless/mildly painful mass (80%), firm, fixed; locations: abdomen (45%), extremities (30%), chest wall (15%)
- **Diagnostic Delay: 12-24 months** (estimated); dismissed as benign fibroma, requires sarcoma specialist not general surgery
- **Ada Surface Ability: 6/10** — Mass detection via self-report; risk factors (FAP, prior surgery) help; requires imaging/specialist

## Strategic Value

- **Company Motivation: 9/10** — HIGHEST strategic priority as newest acquisition; launch excellence critical
- **Opportunity:** Early integrator advantage (Ada partnership as part of launch excellence); partnership with FAP patient registries creates durable referral channels

> ***Pitch Hook:*** *"Desmoids get dismissed as benign lumps for 12-24 months—Ada can change that for your newest acquisition. This demonstrates SpringWorks integration success and rare tumor launch excellence—critical for CEO Beckmann's first major M&A."*

# NOT SUITABLE: MAVENCLAD (Cladribine) - Multiple Sclerosis

## Tier: NO | Fit Score: 4/10 | Generic Entry Eliminated Economics

**Rationale:** US generic entry (March 2026) collapsed per-patient revenue from $32,400 to $5,000-$10,000, reducing PF fees to $400-$1,200—insufficient to justify Patient Finder program. While international markets (EU, Asia) retain exclusivity through 2027-2028, the 12-24 month window is too short for Ada program development and scale.

**Pre-Generic Potential (Historical Reference):** 1,200 undiagnosed drug-addressable patients annually (USA); 40% initial misdiagnosis, median 1-2 year delay. Ada surface ability was 6/10 (MS symptoms detectable but non-specific).

**Recommendation: DO NOT PURSUE** for Mavenclad. Monitor for re-engagement if Merck develops next-gen cladribine formulation with new patents.

# NOT SUITABLE: GONAL-F (Follitropin Alfa) - Fertility

## Tier: NO | Fit Score: 2/10 | No Diagnostic Delay Dynamic

**Rationale:** Fertility treatment has **no diagnostic delay or underdiagnosis** issue. Patients actively seek care after 12 months of unsuccessful conception. The barrier is **ACCESS** (cost, insurance coverage, clinic availability), not patient identification.

**Market Context:** Gonal-f revenue ~$1.4-1.6B (2024), market leader in fertility; biosimilars eroding pricing in EU. Ada Patient Finder model does not apply—patients self-identify as infertile.

**Recommendation: DO NOT PURSUE** for Gonal-f or fertility portfolio. Focus: Access programs and biosimilar defense, not patient finding.

# Strategic Recommendations

## Launch Strategy

1. **Phase 1 (Months 1-12): Tier 1 Launch**
    - Tepmetko (METex14 NSCLC) — Testing advocacy program
    - Erbitux (Head & Neck Cancer) — Persistent symptom flagging
    - Bavencio (Urothelial Carcinoma) — UTI misdiagnosis intervention
    - **Target:** $13-17M Year 1 revenue, proof of concept
2. **Phase 2 (Months 13-24): Tier 2 Expansion**
    - Add Bavencio MCC, Erbitux CRC, Ogsiveo once operational model proven
    - **Target:** $34-43M Year 2 total revenue

## Key Success Factors

- **Tepmetko:** Partner with oncology practices for NGS testing mandates; measure "testing rate increase" as KPI
- **Erbitux HNSCC:** ENT referral network integration; "persistent symptoms >3 weeks" triggers
- **Bavencio UC:** Urology practice partnerships; "recurrent UTI without positive culture" flags
- **Ogsiveo:** Early engagement critical for CEO integration KPI; FAP patient registry partnerships

## Geographic Expansion

- **DACH Market:** €4-6M annual Ada revenue opportunity across top 3 drugs at 10-20% penetration
- **Rest of World:** Focus EU ex-DACH, Japan, Canada, Australia for $20-30M opportunity
- **Sequencing:** Prove USA model first, then international scale in Year 2-3

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